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PART III

# DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## Food and Drug Administration

■

# ACIDIFIED FOODS AND LOW-ACID CANNED FOODS IN HERMETICALLY SEALED CONTAINERS

## Emergency Permit Control and Current Good Manufacturing Practice

[4110-03-M]

Title 21—Food and Drugs

## CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 75N-0332]

## PART 108—EMERGENCY PERMIT CONTROL

### Acidified Foods

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document prescribes the specific enforcement provisions for exemption from, or compliance with, the emergency permit control system of the Federal Food, Drug, and Cosmetic Act for the production of acidified foods. The primary public health problem with these foods is the possible formation of botulinal toxin, and this regulation will ensure safe manufacturing, processing, and packing procedures.

DATES: Effective May 15, 1979, except for: (1) § 108.25(c)(1) (21 CFR 108.25(c)(1)), concerning registration, which is effective July 16, 1979; (2) § 108.25(c)(2), concerning process filing, which is effective 60 days after registration and before packing any new product; and (3) § 108.25(f), concerning personnel training, which is effective September 16, 1980. Objections by April 16, 1979.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvin R. Johnston, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1514.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30442), the Commissioner of Food and Drugs proposed to establish a new regulation (21 CFR 90.22 before the recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) subjecting pickled, fermented, and acidified foods to regulation under section 404, the emergency permit control provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344). The proposal set forth requirements intended to ensure safe manufacturing, processing, and packing procedures for these foods and to permit the Food and Drug Administration (FDA) to verify that the procedures are being followed. Failure of any establishment to comply with the requirements would constitute a prima facie basis for immediate application of section 404 of the act to that establishment under the procedures established in Part 108 (21 CFR Part 108 (formerly 21 CFR Part 90)), Subpart A.

The agency provided a period of 60 days for the filing of comments on the proposal. In response to a request by three trade associations and by the Spanish Ministry of Trade, the Commissioner further extended the comment period to November 20, 1976 (see the FEDERAL REGISTER of September 22, 1976 (41 FR 41436)). Elsewhere in the July 23, 1976 issue of the FEDERAL REGISTER, the Commissioner proposed to establish current good manufacturing practice regulations for preparing pickled, fermented, and acidified foods (41 FR 30457) and to revise the current good manufacturing regulations for low-acid canned foods (41 FR 30444).

The National Canners Association (now the National Food Processors Association (NFPA)) filed extensive comments on the proposed revocation of the exemption from the definition of low-acid foods for tomatoes, pears, and pineapple having a pH of less than 4.7 and figs having a pH of 4.9 or below. After the comment period closed, NFPA requested that the comment period be reopened to allow that association to develop and submit data to determine the final pH of certain products and/or classes of products that it felt should be exempted from the regulation. The comment period was reopened until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38608).

Nineteen letters, each containing one or more comments, were received from industry, trade associations, State and Federal government agencies, and members of Congress.

Eight of the comments pertain to the proposed revision of the good manufacturing practice regulations for thermally processed low-acid foods packaged in hermetically sealed containers (Part 113 (21 CFR Part 113)) and the proposed good manufacturing practice regulation for pickled, fermented, and acidified foods (Part 114 (21 CFR Part 114)). Those comments and the Commissioner's responses are found in the final orders on those proposals, published elsewhere in this issue of the FEDERAL REGISTER. The remaining comments, summarized, and the Commissioner's responses to them follow:

1. One comment questioned the inclusion of fermented foods in the regulation because, the comment noted, the agency gave no examples in which any proven improper fermentation procedure caused that kind of food to be a health hazard.

The Commissioner has reexamined the basis for the decision to include pickled and fermented foods within this order. No instances of illness as the result of contamination of commercially processed fermented foods with *Clostridium botulinum* have been reported in the United States. In addition, the Commissioner has contacted health authorities in Canada, Japan, the United Kingdom, and other members of the European Economic Community concerning this problem (the correspondence is on file in the office of the Hearing Clerk, FDA). No cases of botulism caused by commercially processed fermented foods have been reported in those countries. In the absence of known illnesses or deaths from commercially prepared fermented foods, the Commissioner has concluded that the regulation should apply only to acidified foods. Because pickled foods include those pickled by fermentation or by acidification, the Commissioner has dropped the word "pickled" from the title but advises that pickled foods prepared by acidification are considered acidified foods and are subject to this order. Moreover, in the event that illness due to commercially prepared fermented foods does occur, the Commissioner will reconsider this decision. The final regulation reflects this change.

The function of these regulations is to protect the public from the danger of botulism poisoning associated with acidified foods. Accordingly, the Commissioner considers it appropriate to consider precisely what foods are subject to this regulation. Among the principal factors that control the gowth of *C. botulinum* in food are pH, water activity, and storage conditions. As the Commissioner notes in the document in this issue of the FEDERAL REGISTER concerning current good manufacturing practice regulations for low-acid canned foods, *C. botulinum* will not grow in food that has a pH of 4.6 or below. Similarly, evidence shows that food with a water activity value that is 0.85 or below also will not permit *C. botulinum* to grow. This regulation and the current good manufacturing practice regulations for acidified foods, published elsewhere in this issue of the FEDERAL REGISTER, are intended to ensure that naturally low-acid foods, which use acidification as the means of protecting against *C. botulinum* growth, are properly acidified. Accordingly, all foods that are intended to be acidified to a finished equilibrium pH of 4.6 or below and

that have a water activity greater than 0.85 are subject to this regulation and the current good manufacturing practice regulations (21 CFR Part 114) which the Commissioner is also promulgating.

2. Four comments questioned the Commissioner's authority under section 404 of the act to impose emergency permit control restrictions for pickled, fermented, and acidified foods. One comment maintained that the Commissioner's authority to impose emergency permit control restrictions under section 404 is limited to situations in which a potential for contaminating a class of food with microorganisms is sufficiently great to warrant extraordinary processing restrictions as a preventive measure. The comment argued that pickled, fermented, and acidified foods are not such a class of foods.

A second comment stated that under section 404 of the act the Commissioner can impose emergency permit control upon a company or an industry only when the following conditions are met: (1) The Secretary (or delegate) has conducted an investigation of a class of food; (2) that investigation reveals an emergency situation, that is, a clear and present danger to the public health because that class of food is contaminated with microorganisms; (3) the danger cannot adequately be determined after the food has entered interstate commerce; and (4) the Secretary then, and in that case only, issues temporary regulations imposing emergency permit control on the affected industry. Therefore, the comment argued, the Commissioner can impose an emergency permit control only in rare instances of an emergency nature, only after investigation, only on a temporary basis, and only when other sections of the act are inadequate to protect the public. The comment also alleged that FDA has not conducted any investigation and is not faced with an emergency for which other sections of the act are inadequate to protect the public; to support this allegation, the comment pointed out that there have been no cases of botulism from commercially produced pickles.

Another comment contended that the adulteration and misbranding provisions of the act, and the regulations promulgated under those sections, are more than adequate to deal with the problems discussed in the proposal. Finally, one comment stated that the Commissioner does not have the authority under the act to require "(1) registration of food processing plants; (2) establishment and filing of 'scheduled processes'; (3) maintenance of records of equipment calibration and testing; (4) specific food manufacturing processes; (5) product coding; (6) maintenance of processing and production records; (7) setting aside and reworking certain batches of product; and (8) sending supervisory personnel to approved schools."

The Commissioner notes that this regulation brings acidified foods within the scope of the emergency permit control section of the act and the regulations. It establishes criteria that a manufacturer of those foods must satisfy to maintain an exemption from the factory permit requirement. The criteria are the same as those established for thermally processed low-acid canned foods in Part 108. Briefly, the regulation requires every commercial processor engaged in processing or packing acidified foods to (1) register and file its processing method with FDA; (2) process the foods in accordance with the filed process; (3) provide FDA with information to determine the adequacy of the processing; (4) report to FDA any spoilage, process deviations, or contamination that may have health significance, when any part of affected lots has reached the channels of interstate commerce; (5) develop for use by it and the distributors of its products a recall procedure that includes product coding and FDA notification; (6) prepare, retain, and review specific records and make them available to FDA upon written demand; and (7) operate only under the supervision of persons who have attended FDA-approved schools for appropriate food processing.

Arguments that the Commissioner lacks authority to regulate food in the manner described in Part 108 were raised and rejected when the Commissioner first established this procedure to regulate low-acid canned foods (see the FEDERAL REGISTER of May 14, 1973 (38 FR 12716) and January 29, 1974 (39 FR 3750)). To recapitulate, the Commissioner has reviewed the legislative history of the act and concludes that section 404 of the act gives the Commissioner the authority to establish the system set out in Part 108 for dealing with the threat of botulism in acidified foods. The act is remedial and should be construed in a manner consistent with its overriding public health protection function. The legislative history of the emergency permit control system shows that Congress intended to develop a regulatory scheme to protect the public from virulent foodborne diseases that cannot be controlled by routine inspection procedures. Botulism was the principal disease cited. Congress authorized a rulemaking procedure to enable FDA to develop the facts for determining whether a specific class of food should be subject to the emergency permit control system, unless that food is manufactured in accordance with the strict requirements which the agency can prescribe. Furthermore, the requirements can be more stringent than the current good manufacturing practices of the industry involved, and FDA can tailor current good manufacturing practice regulations for any specific industry that poses a problem.

On the basis of experience in regulating the low-acid canned food industry, the Commissioner concludes that the requirements set forth in this regulation are appropriate and necessary for (1) adequate monitoring of the acidification of food and (2) expeditious revocation of the exemption from the requirement for a temporary emergency permit to manufacture acidified foods. These two factors are necessary to protect the public from botulinal food poisoning. Based on the evidence adduced thus far, the Commissioner believes that there is every reason to subject acidified foods to the requirements of Part 108.

As comments noted, the term "pickled foods" encompasses both acidified and fermented foods. As discussed earlier in this preamble, the Commissioner has concluded that the regulation should be applicable only to acidified foods. In the preamble to the proposal, the Commissioner described two specific instances of botulinal food poisoning caused by commercially processed acidified foods in the United States, in which eight people became ill. Material on file concerning the other incidents described in the earlier preamble shows that the processors of pickled and acidified foods appear to lack an awareness of the importance of proper technical processing of these foods. Thus, numerous cases of botulism have occurred in commercially produced acidified foods, the class of foods defined in new Part 114 (21 CFR Part 114). Furthermore, since publication of the proposal there have been other reported outbreaks of botulinal poisoning attributable to improper acidification of commercially processed foods. The Oklahoma State epidemiologists and experts at the Center for Disease Control in Atlanta, Georgia, identified seven persons with clinical symptoms of botulism which was attributed to the consumption of commercially canned acidified sweet cherry peppers in a restaurant in Oklahoma in April 1976. The Food and Drug Administration agreed that the illnesses were caused by the canned cherry peppers, and it classified the recall of the incriminated product as a Class I recall. An outbreak of 45 cases of botulism was recorded as the result of consumption of improperly acidified and processed food in a restaurant in Michigan in 1977. As of October 27, 1977, a total of 29 foreign shippers had been identified as not controlling the pH of acidified low-acid canned foods. Therefore,

the Commissioner finds ample data to support the promulgation of this regulation as it concerns acidified canned foods. Copies of the pertinent data are on file with the Hearing Clerk, FDA.

3. One comment contended that the two botulism poisoning episodes associated with commercially prepared pickled and acidified foods mentioned in the preamble to the proposed regulation are clearly an insufficient basis for evoking the extraordinary powers of section 404 of the act. The comment further argued that the reported cases of botulism associated with pickled, home-canned products cited in the preamble are irrelevant to the proposed restrictions on commercial processing.

The Commissioner rejects the comment. The potential hazard due to botulism from pickled and acidified foods is just as great as, if not greater than, the hazard of botulism associated with low-acid canned foods. The deaths and other poisoning cases described in paragraph 2 of this preamble and in the preamble to the notice of proposed rulemaking are evidence to support the rule. In the Commissioner's opinion, the data on home-canned foods are relevant because they demonstrate a considerable potential for producing unsafe food if the producer fails to maintain proper critical factors.

4. One comment requested the Commissioner to delay implementing the proposed regulations until a public hearing is held.

The Commissioner advises that a hearing is inappropriate at this time. The regulation is being promulgated under section 701(e) of the act (21 U.S.C. 371(e)), under which interested parties have 30 days to file objections to the final order and supporting data under § 12.22 (21 CFR 12.22). The Commissioner will evaluate any objections and data received and will decide whether the objections raise genuine and substantial factual issues whose resolutions require a hearing. A hearing will be held and the regulation delayed only if legally adequate objections are filed.

5. One comment attacked the regulation as it applies to imported food. The comment argued that the regulation discriminates against imported food and foreign processors and favors domestic food and domestic processors. The comment also questioned whether section 801 of the act (21 U.S.C. 381) permits the Commissioner to prevent importation of food that fails to comply with section 404 of the act. The comment argued that, to the extent used to prevent importation of acidified food, the regulation constitutes a nontariff trade barrier that violates the General Agreement on Tariff and Trade, a problem exemplified by the requirement for registration and the process filing before importing.

The Commissioner disagrees. The comment shows a misunderstanding of the application of the regulation and section 801 of the act. First, the Commissioner has found a number of imported, commercially processed foods that have been improperly acidified. From April 1975 to October 1976, the Commissioner also identified 31 foreign processors that failed to control the pH of their products at levels sufficient to protect the public health. For these reasons, and for the reasons described in paragraph 1 of this preamble, the commissioner concludes that there are sufficient grounds for imposing the requirements of section 404 of the act on imported acidified foods. Therefore, all foreign and domestic processors of acidified foods shall register and file their scheduled processes with FDA before their foods can be imported to this country. Because the agency is applying the regulation uniformly to all acidified foods and processors of acidified foods, both foreign and domestic, the commissioner finds no basis for contending that the regulation constitutes a trade barrier.

When FDA determines, after investigation, that a domestic manufacturer, processor, or packer of an acidified food has not met or does not meet the mandates of this regulation or other provisions of Part 108, the agency may have to require that party to obtain and hold an emergency permit. In that case, FDA will issue an order to the manufacturer, processor or packer under § 108.5 (21 CFR 108.5), explaining that the party must hold a permit before it can introduce food, or deliver food for introduction, into interstate commerce. Until the agency issues a permit, the manufacturer, processor, or packer may not introduce, or deliver for introduction, into interstate commerce any such food manufactured, processed, or packed by it, except as provided by the rigid provisions of § 108.19 (21 CFR 108.19). Similary, when the Commissioner determines, after investigation, that the foreign processor of an imported acidified food, or the imported food itself, does not meet the requirements of this regulation or of new Part 114, the Commissioner will request the Secretary of the Treasury to refuse admission of that food into the United States, under section 801 of the act.

Acidified food that has been manufactured, processed, or packed under conditions that fail to comply with the requirements established by this regulation and by Part 114 has been processed under inadequate, i.e., insanitary conditions. Therefore, prohibiting the importation of this potentially adulterated and unsafe food is appropriate because the introduction or delivery for introduction of adulterated food or foods in violation of section 404 of the act is a prohibited act under section 301 of the act (21 U.S.C. 331). The Commissioner did not intend to discriminate against importers, and to make it clear that both domestic and foreign processors have the same time to register and file their processes with FDA before thay offer their products to consumers, the Commissioner has reworded § 108.25(c)(1) and (2) to give both domestic and foreign processors 120 days after the effective date of this regulation to register with FDA and 60 days after registration to file their processes. These requirements are the same for importers of low-acid canned foods.

6. One comment suggested that proposed § 108.25(c)(2)(i) be revised to permit processors to establish processes that exceed the safety requirements established under Part 114.

The Commissioner agrees and has so changed this provision, which is now § 108.25(c)(3)(i).

7. Two comments requested that § 108.25(f) be changed to exempt from further schooling all persons certified before March 16, 1979 as having attended a school approved by the Commissioner for giving instruction in retort operations, processing system operations, aseptic processing and packaging systems operations, and container closure inspections.

The Commissioner agrees and has reworded this provision to al[illegible] persons certified before the publi[illegible] of this final regulation to be exempt from the schooling requirement. However, the Commissioner notes that a course including more details on acidification of foods is advisable for persons involved in the processing of such foods to ensure that they are knowledgeable in this process.

8. The State of California requested the Commissioner to rule that compliance with State regulations which California intends to promulgate on pickled, fermented, and acidified foods constitutes compliance with § 108.25.

The Commissioner cannot grant such a request until a State has promulgated, and the agency has reviewed, such regulations. But the Commissioner has added a new paragraph (i) to § 108.25 to enable California, or any other State that regulates the commercial processing of acidified foods, to promulgate regulations that coordinate with those of FDA. When the Commissioner finds that a State has promulgated effective regulations specifying at least the requirements of Part 114 for the regulation of the commercial processing of acidified foods, the agency will issue a notice stating that compliance with the State regula-

tions constitutes compliance with Part 114.

9. One comment requested that, if a processor has filed information with FDA on forms FD-2541, 2541a, 2541b, or 2541c as required under § 108.35 (for low-acid canned foods), there should be no need for that processor to submit new form FD-2962.

The Commissioner agrees and has substituted forms FD-2541 and 2541c for the proposed form FD-2962. Any processor that has registered its establishments on form FD-2541 and filed its processes on forms FD-2541a, b, or c, need not reregister or refile its processes. Processors must file new processes or changes in processes, however, on form FD-2541c.

10. Some comments questioned whether commercial processor that operate pilot plants, producing samples of acidified foods for market or consumer testing, need file their processes with FDA.

The Commissioner points out that foods produced in these plants must be processed in accordance with good manufacturing practices so that they do not present the potential public health hazard that this regulation is being promulgated to prevent. To protect the public adequately, the Commissioner concludes that pilot plant processes must be filed with FDA in the same manner as those for any other commercially prepared acidified food. An identical regulation (§ 108.35 (21 CFR 108.35)) applies to sampling and testing operations making low-acid canned foods.

11. One comment claimed that the added cost of the paperwork involved in this regulation would eliminate many small part-time producers in the United States. The comment further contended that the regulation would virtually eliminate all imports of specialty canned and bottled foods, thereby eliminating the jobs of small food importers.

The Commissioner doubts that this will be the case. Many of the products and processors, both domestic and imported, are currently subject to § 108.35 (21 CFR 108.35) for low-acid canned foods and have been for several years. In certain cases losses have occurred, but they did so because the producer did not have a safe product. The minimal cost of the paperwork is a small price to pay to ensure that food is safe for the American consumer.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 402, 404, 701(e), 52 Stat. 1046-1047 as amended, 1048, 70 Stat. 919 (21 U.S.C. 342, 344, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 is amended in Part 108 by adding to Subpart B a new § 108.25 as follows:

**§ 108.25 Acidified foods.**

(a) Inadequate or improper manufacture, processing, or packing of acidified foods may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, to protect the public health, it may be necessary to require any commericial processor, in any establishment engaged in the manufacture, processing, or packing of acidified foods, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and filing of process information, and the mandatory portions of §§ 114.10, 114.80(a) (1) and (2), and (b), 114.83, 114.89, and 114.100 (b), (c), and (d) of this chapter as they relate to acidified foods. These requirements are intended to ensure safe manufacturing, processing, and packing processes and to permit the Food and Drug Administration to verify that these processes are being followed. Failure to meet these requirements shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, under the procedures established in Subpart A of this part.

(b) The definitions in § 114.3 of this chapter are applicable when those terms are used in this section.

(c) (1) *Registration.* A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any State, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FD-2541 (food canning establishment registration) information including, but not limited to, the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment. These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, DC 20204. Commercial processors presently so engaged shall register within 120 days after the effective date of this regulation. Foreign processors shall register within 120 days after the effective date of this regulation or before any offering of foods for import into the United States, whichever is later. Commercial processors duly registered under this section shall notify the Food and Drug Administration not later than 90 days after the commercial processor ceases or discontinues the manufacture, processing, or packing of the foods in any establishment, except that this notification shall not be required for temporary cessations due to the seasonal character of an establishment's production or by temporary conditions including, but not limited to, labor disputes, fire, or acts of God.

(2) *Process filing.* A commercial processor engaged in the processing of acidified foods shall, not later than 60 days after registration, and before packing any new product, provide the Food and Drug Administration information on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size. Filing of this information does not constitute approval of the information by the Food and Drug Administration, and information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on form FD-2541c (food canning establishment and process filing for other than still retort and agitating processes). Forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, D.C. 20204, or at Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, D.C. 20204.

(3) *Process adherence and information*—(i) *Scheduling.* A commercial processor engaged in processing acidified foods in any registered establishment shall process each food in conformity with at least the scheduled processes filed under paragraph (c)(2) of this section.

(ii) *Process and pH information availability.* When requested by the Food and Drug Administration in writing, a commercial processor engaged in the processing of acidified foods shall provide the Food and Drug Administration with any process and proce-

dure information that the Food and Drug Administration deems necessary to determine the adequacy of the process. Furnishing of this information does not constitute approval by the Food and Drug Administration of the content of the information filed, and the information concerning processes and other data so furnished shall be considered trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905 (to the extent that they qualify under those provisions).

(d) A commercial processor engaged in the processing of acidified foods shall promptly report to the Food and Drug Administration any instance of spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance, where any lot of such food has in whole or in part entered distribution in commerce.

(e) A commercial processor engaged in the processing of acidified foods shall prepare and maintain files on a current procedure for use for products under the processor's control, which that processor will ask the distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying the Food and Drug Administration of any recalls; and for implementing recall programs.

(f) All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction. The Commission will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and Part 113 of this chapter before March 16, 1979, as having satisfactorily completed the prescribed course of instruction under this section and Part 114 of this chapter. The Commissioner will not withhold approval of any school qualified to give such instruction.

(g) A commercial processor engaged in the processing of acidified foods shall prepare, review, and retain at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture, all records of processing, deviations in processing, pH, and other records specified in Part 114 of this chapter. Upon written demand during the course of a factory inspection under section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by that employee of these records to verify the pH and the adequacy of processing.

(h) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Quality Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 et seq.)).

(i) Wherever the Commissioner finds that any State regulates the commercial processing of acidified foods under effective regulations specifying at least the requirements of Part 114 of this chapter, the Commissioner shall issue a notice stating that compliance with such State regulations shall constitute compliance with this section, if the State through its regulatory agency or each processor of acidified foods in the State files with the Food and Drug Administration the registration information and the processing information prescribed in paragraph (c) of this section.

(j) Imports: (1) This section applies to any foreign commercial processor engaged in the processing of acidified foods and offering those foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, under section 801 of the act, to any acidified foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any acidified food so refused admission shall not be admitted until the Commissioner determines that the commercial processor offering the food for import has complied with the requirements of this section and that the food is not injurious to health. To assist the Commissioner in making this determination, a duly authorized employee of the Food and Drug Administration shall be permitted to inspect the commercial processor's manufacturing, processing, and packing facilities.

(k) The following information submitted to the Food and Drug Administration under this section is not available for public disclosure unless it has been previously disclosed to the public as defined in § 20.81 of this chapter or it relates to a product or ingredient that has been abandoned and no longer represents a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar information, except that any compilation of the information aggregated and prepared in a way that does not reveal information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

Any person who will be adversely affected by this regulation may at any time on or before April 16, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections to it and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection if a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* Except for the provisions of § 108.25(c)(1) concerning registration, which shall become effective July 16, 1979; § 108.25(c)(2), concerning process filing, which shall become effective 60 days after registration and before packing any new product; and § 108.25(f), concerning personnel training, which shall become effective September 16, 1980; and except for any provisions that may be stayed by the filing of proper objections, compliance with this final regulation will be required by May 15, 1979. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

(Secs. 402, 404, 701(e), 52 Stat. 1046-1047 as amended, 1048, 70 Stat. 919 (21 U.S.C. 342, 344, 371(e)))

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 79-7687 Filed 3-15-79; 8:45 am]

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[4110-03-M]

[Docket No. 75N-0333]

## PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

### Current Good Manufacturing Practice

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document revises the specific current good manufacturing practices (CGMP's) for canning low-acid foods. The primary public health problem associated with these foods is the possibility of botulinal toxin formation, and these revised regulations will ensure safe manufacturing, processing, and packing procedures for low-acid canned foods in hermetically sealed containers.

EFFECTIVE DATE: May 15, 1979.

ADDRESS: Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30444), the Commissioner of Food and Drugs proposed to revise the current good manufacturing practice regulations for low-acid canned foods now in Part 113 (21 CFR Part 113) (formerly 21 CFR Part 128b, before the recodification of March 15, 1977 (42 FR 14302)). The Commissioner provided a period of 60 days for filing comments on the proposal. In response to a request by three trade associations and by the Spanish Ministry of Trade, the Commissioner extended the comment period to November 20, 1976 in a notice published in the FEDERAL REGISTER of September 22, 1976 (41 FR 41436).

The National Canners Association (now the National Food Processors Association (NFPA)), the original petitioner for this regulation in 1971, had extensive comments opposing the proposed change to remove the exemptions from the definition of low-acid canned food for tomatoes, pears, and pineapples having a final equilibrium pH of less than 4.7 and figs having an equilibrium pH of 4.9 or below. After the close of the comment period, NFPA requested that the comment period be reopened so that it could develop and submit data to determine the final equilibrium pH of certain products or classes of products that could be exempted from the scope of the regulations and so that it could submit additional data on the use of flow diversion valves in aseptic canning. The Commissioner reopened the comment period until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38608). The agency later received from NFPA, and placed on public file, comments and data supporting its position on tomatoes and figs. However, the Food and Drug Administration (FDA) received no comments concerning pears or pineapples or the use of flow diversion valves in aseptic canning.

In all, FDA received 24 letters, each containing one or more comments, from industry, trade associations, universities, a Federal government agency, members of Congress, and an individual.

Five comments dealt with the Commissioner's proposals on emergency permit control regulations and current good manufacturing practice regulations for pickled, fermented, and acidified foods, which were published in the same July 23, 1976 issue of the FEDERAL REGISTER (41 FR 30441 and 30457, respectively) as proposed § 90.22 (21 CFR 90.22) (now § 108.25 (21 CFR 108.25)) and Part 128g (21 CFR Part 128g) (now Part 114 (21 CFR Part 114)), respectively. Responses to these comments are contained in the preambles to the final regulations resulting from those proposals, referred to below.

The regulations as amended by this document in Part 113 are designed to update the current good manufacturing practices for low-acid canned foods—foods that present a documented threat of *Clostridium botulinum*. Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner (1) is issuing a regulation, 21 CFR 108.25, that, because of the threat of *C. botulinum* from such foods, subjects acidified foods to the emergency permit control system under section 404 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344); and (2) is promulgating regulations, 21 CFR Part 114, that articulate the current good manufacturing practices for the preparation of acidified foods. The factors used to classify a food as low-acid or acidified, or to exempt it from the categories, are identical, although the categories are discrete. Because the relationships can be confusing, the Commissioner believes it worthwhile to discuss the factors that control *C. botulinum* and their use in categorizing the foods.

The primary factors that control the growth of *C. botulinum* in food are pH, water activity, and storage conditions. *C. botulinum* requires anaerobic atmosphere, and ambient temperature favors its growth. Acidity and pH vary inversely. *C. botulinum* growth is normally prevented in food with a pH of approximately 4.8 or below. The FDA and the food processing industry have historically added a safety factor of 0.2 pH unit, and they have recognized the basic discriminating pH as 4.6 (see the FEDERAL REGISTER of November 12, 1971 (36 FR 21688) and January 24, 1973 (38 FR 2398)). Foods with a pH above 4.6 are considered low-acid foods. All naturally occurring acid-foods (i.e., those foods with a pH of 4.6 or below) present no risk of botulism and therefore are not subject to the requirements of Part 113.

Most fruits have a naturally occurring pH well below 4.6 and are acid foods. They are therefore not subject to regulation as low-acid foods under Part 113 or as acidified foods under Part 114.

Water activity, the measure of free moisture in the food, is the second major factor that restricts *C. botulinum* growth. As the water activity increases, botulism growth becomes more likely if the pH of the food is above 4.6 Ohye and Christian, and Troller (see Refs. 7, 9, 10, and 11 in the preamble to the proposed CGMP's for pickled, fermented, and acidified foods (41 FR 30457, July 23, 1976), which are on file with the Hearing Clerk) have shown that foods with a water activity that is equal to or less than 0.85 present no risk of botulism growth, regardless of the food's pH. The 0.85 factor carries an appropriate margin of safety. Therefore, foods whose water activity is equal to or less than 0.85 are not subject to the provisions of this part or of Part 114.

Some fruits do have a naturally occuring pH that is above 4.6, and they are thus considered to be low-acid foods. All of these fruits and other low-acid foods intended for processing and packaging in hermetically sealed containers are subject to regulation under this part and § 108.35 (21 CFR 108.35) if their water activity is greater than 0.85. In these foods, botulism is controlled by heat treatment, and this document prescribes good manufacturing practices for thermally processing these low-acid foods packaged in hermetically sealed containers. Other foods have a naturally occurring pH that is above 4.6, and processors of these foods may control the growth of *C. botulinum* in them by intentionally acidifying the food to a pH

of 4.6 or below. Such foods are considered acidified foods, and if they have a water activity value that is above 0.85, they are subject to regulation under § 108.25 and Part 114. If the food is intended to be acidified only to a pH of 4.7, it is considered a low-acid food and subject to regulation as such. The following table illustrates the relationships between pH, water activity, and regulatory status of most foods.

| pH (final equilibrium) | $a_w$ | Low-acid (21 CFR 113) | Acidified (not naturally) (21 CFR 114) |
|---|---|---|---|
| <4.5 | ≤0.85 | No | No |
| <4.5 | >0.85 | No | Yes |
| 4.6 | ≤0.85 | No | No |
| 4.6 | >0.85 | No | Yes |
| ≥4.7 | ≤0.85 | No | No |
| ≥4.7 | >0.85 | Yes | No |

Low-acid foods that are not subject to these regulations are low-acid foods packaged in containers that intentionally provide an aerobic atmosphere (containing oxygen). When improperly processed or stored, these foods spoil, but they normally do not present a risk of botulism.

The remaining comments are summarized, and the Commissioner's responses are given, below.

1. In the proposal the Commissioner stated that the growth of spore-forming microorganisms in a product can be prevented by the control of water activity ($a_w$), the use of salt, sugar, or other chemicals, or some unique characteristic of the food, and that the growth of non-spore-forming microorganisms can be controlled by a thermal process that is insufficient to destroy the spore-forming microorganisms. Then the Commissioner cited examples. Based on this discussion, three comments requested that processed cheese be excluded from the regulation. One comment asked that caviar be excluded, and another, that sirups be excluded.

The Commissioner recognize that a proper combination of heat and $a_w$ will produce a safe product. But processors of all foods that rely on a combination of pH, water activity, and other factors to produce foods that present essentially no risk from *C. botulinum* must file their processes with FDA, and the material filed must show that the spores and spore-forming microorganisms will not grow in the product. The material filed also must show that the heat processes will be adequate to destroy the vegetative cells that might grow in such products. No data have been filed with FDA to demonstrate that microorganisms of public health significance will not grow in the foods for which specific exemptions from the regulations were requested by the comments, and the Commissioner has no basis for exempting those foods from the regulations. Therefore, all processors of foods such as processed cheese, caviar, and sirups must register their plants and file their processes as directed in § 108.35 and comply with all other provisions of this part if the $a_w$ of the food is greater than 0.85 and the pH is above 4.6. To clarify any arguable misunderstanding, the Commissioner has expanded § 113.81(f) (formerly 128b.3(f)) to specify its applicability to low-acid foods that have a water activity of greater than 0.85.

DEFINITIONS

2. "Commercial processor" (§ 113.3(d)): Questions have been asked concerning whether or not manufacturers of samples of low-acid canned foods intended for consumer tests and test marketing are within the scope of these regulations.

Because such food is being produced for human consumption, the Commissioner concludes that consumers of the test-marketed food are entitled to the same public health protection as consumers of other canned foods. The Commissioner has, therefore, clarified the definition of "commercial processor" to include persons producing foods for use in market or consumer tests.

3. "Commercial sterility" (§ 113.3(e)): One comment suggested that "the definition should be reworded to allow the implementation of the Commissioner's desires to incorporate foods in which the water activity or other inhibiting agents prevent growth of spore-forming microorganisms." The comment further suggested that the definition be reworded as follows:

> Commercial sterility of thermally processed food means the condition achieved by application of heat which renders such food free of viable forms of microorganisms, of public health as well as nonhealth significance, capable of reproducting in the food under normal nonrefrigerated conditions of storage and distribution.
>
> Commercial sterility of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of microorganisms, of public health as well as nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

The Commissioner intended the definition of commercial sterility of thermally processed food to include foods in which water activity is used to prevent the growth of spore-forming microorganisms. Therefore, the Commissioner has revised the definition to clarify this point. Thermally processed foods, whether rendered commercially sterile by heat alone or by controlling water activity together with the application of heat, must be free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. The Commissioner has also changed the regulation to clarify that foods in which water activity prevents the reproduction of spores of microorganisms of public health significance may contain spores that cannot reproduce because of low water activity. However, foods that are sterilized by heat alone may not contain any living microorganisms (including spores) of public health significance.

Concerning the definition of commercial sterility of equipment and containers used for aseptic processing and packaging of food, the Commissioner sees no substantial differences between the suggested wording and that published in the proposal and thus has made no changes in the definitions.

4. "Low-acid foods" (§ 113.3(n)).

a. The proposal would have revoked the exemption from the definition of low-acid canned food that exists in the current regulations for tomatoes, pears, pineapples, and figs. In its initial comments, NFPA requested that the exemption be maintained until additional data were available to show that the exemption is appropriate. Data were later presentd to demonstrate that the outgrowth of *C. botulinum* is prevented in tomato products with an equilibrium pH of less than 4.9. Data on figs were also submitted.

The United States Department of Agriculture (USDA) Eastern Regional Researh Center in Philadelphia, Pennsylvania, conducted research on the acidity of numerous tomato varieties, which it submitted as a comment on the proposed changes in the regulations. Its 1975 study found no tomato samples having a population mean pH higher than 4.55, and no individual fruits having a pH of 4.8 or higher; in its 1976 study, some of the individual tomatoes exceeded a pH of 4.8. The USDA also commented that the proposed rules did not specify whether the required pH is to be the pH of a composite of raw material, the mean of replicate analysis of different raw material units, or some other value.

The Commissioner proposed to define a low-acid food as one with a finished equilibrium pH of greater than 4.6, and the current regulation also uses the term "finished equilibrium pH." For this reason, the Commissioner believes that the pH discriminate established by the regulation is clear; it is the equilibrium pH of the finished food, not the pH of a composite of raw material or the mean of replicate analysis of different raw material units. The Commissioner also notes that the USDA studies show that some varieties of tomatoes have a pH greater than 4.7. The need to exercise a high degree of care in the processing

and pH control of tomato products is obvious.

Based on the tomato data submitted by NFPA, the Commissioner concludes that in tomato products a finished equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum;* accordingly, the Commissioner has retained the exemption from the definition of low-acid foods for tomatoes and tomato products having a finished equilibrium pH less than 4.7 which includes a safety factor of 0.2 pH unit.

The Commissioner, however, believes the data for figs are inconclusive and is revoking their exemption with this order. Therfore, figs are low-acid foods that are subject to manufacture in accordance with this part, but if the figs are acidified to a pH of 4.6 or below, they are regulated as acidified foods under Part 114. The FDA evaluation of these data has been placed on display for public review at the office of the Hearing Clerk, FDA (address above).

Because no data were submitted to support the exclusion of pears and pineapples from the requirements of the regulations, no change has been made in the definition, and the exemption has been removed.

b. Another comment asked that the water activity requirement be changed from 0.85 to 0.92.

The Commissioner advises that some vegetative forms of microorganisms of public health concern are not inhibited at an $a_w$ of 0.92. A thermal process adequate to destroy these microorganisms in products having an $a_w$ above 0.85 must be established by a competent processing authority. Therefore, the Commissioner has not made the suggested change in the water activity provision of the definition for low-acid foods.

PERSONNEL

5. One comment suggested that the parenthetical phrase "including systems wherein water activity is used in conjunction with thermal processing" be deleted from the requirement for supervision schooling because this subject is adequately covered with the statement "instruction appropriate to the preservation technology involved."

The Commissioner believes that the supervisor of a process in which water activity is used as a part of the thermal process must have some knowledge of the role of water activity in that process. To emphasize the point, the Commissioner declines to make this change in the regulation.

EQUIPMENT AND PROCEDURES

6. Temperature-recording device (§ 113.40(a)(2)): Three comments agreed that the temperature chart of the recording device should closely agree with the known accurate mercury-in-glass thermometer. However, all three objected to the requirement that the temperature chart recording never be higher than the mercury-in-glass thermometer. One comment stated that, because of the difference in response times between the temperature recorder bulb and the mercury-in-glass thermometer, the recorder temperature might momentarily be above that of the mercury-in-glass thermometer. The other two comments asked that the wording in the current regulation, which allows the recorder reading to be within 1° F of the mercury-in-glass thermometer reading, be restored. They argued that slight changes should not be considered a processing deviation.

The Commissioner rejects the comments because it is in the interest of public safety that the recorder temperature be no higher than the mercury-in-glass thermometer readings. The current regulation might lead to an erroneous conclusion about the potential hazard associated with the processing that has actually occurred. The Commissioner advises, however, that small momentary variations in which the temperature indicated by the recorder may be slightly above the mercury-in-glass thermometer reading, will not be considered deviations.

The same three comments also objected to the proposed requirement for an air supply to the temperature controllers that is separate from the air supply to the rest of the plant. They argued that the manner in which clean dry air is obtained should be left to the discretion of the packer.

The Commissioner agrees and has deleted the proposed requirement from this and the other sections in which it was proposed.

7. Pressure gages (§ 113.40(a)(3)): A comment objected to the Commissioner's proposal for deleting the requirement for a pressure gage on retorts and gave several reasons why the operator needs to know the pressure in the retort. The reasons stated were: (1) The steam retort is a hazardous device, and the operator must know the pressure in the retort to ensure a safe operation of the device; (2) under certain operating conditions, a superheated steam condition can exist in the steam retort, and only with the pressure gage can the operator identify that condition; (3) automatic control devices occasionally fail, and the pressure gage is the only device that will immediately indicate that a failure is occurring; and (4) the readings of an accurate pressure gage can be converted into temperature and the pressure gage therefore offers another point of measurement and control.

The Commissioner's statement in the preamble to the proposed regulation remains valid: The pressure gage serves no mandatory function in the thermal processing of low-acid canned foods. However, for the reasons given in the comment, the pressure gage may serve a function, and the Commissioner has retained the wording of the proposal which makes the pressure gage optional.

8. Steam spreaders (§ 113.40(a)(7)): One comment suggested that the wording of this section be changed to permit retorts in which steam is allowed to enter the top or the bottom as long as the vent is opposite the steam inlet. This comment and two others also asked the Commissioner to make clear that the number of perforations in the spreaders be such that the total cross-sectional area of the perforations be equal to 1½ to 2 times that of the smallest restriction in the steam inlet.

The Commissioner agrees with both suggestions and has made the appropriate changes. In the Commissioner's opinion, that formula is appropriate to maintain the proper distribution of steam for sterilization.

9. Bleeders (§ 113.40(a)(8)): One comment suggested rewording this section to clarify precisely where near the "end of the shell of the retort" the bleeders should be. The comment stated that the need for bleeding of steam arises in areas that contain cans, and it suggested the following change for horizontal still retorts: "Bleeders shall be located within one foot of the outmost location of containers in the retort."

The Commissioner agrees and has made the appropriate change in the regulation.

10. Air valves and water valves (§ 113.40(a) (10) and (11)): One comment asked for a specific list of the types of air and water valves that are acceptable for use in the cooling of retorts.

The Commissioner advises that there are a number of suitable valves which may be used, and each processor must pick the proper valve for its process. Therefore, the Commissioner believes that the variables render a list inappropriate and has made no change.

11. Critical factors (§ 113.40(a)(13)):

a. The regulation requires that critical factors such as consistency, percent solids, and fill-in or drained weight, which are usually determined at a location some distance from the retort, be recorded on the processing record. One comment suggested deleting this requirement.

The Commissioner agrees that it is unnecessary to carry all test results back to the retort room, but this information is important and must be combined at some time (but not necessarily rewritten) in one place. This point

is all that is required by the regulation, and in the Commissioner's opinion it is clear. Therefore, the Commissioner has retained the wording in the regulation to avoid a misunderstanding of what actually is required.

b. Section 113.40(a)(13)(iii): One comment protested that it is unnecessary to make measurements and recordings of all critical factors at intervals of 15 minutes or less.

Measurements and recordings at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process are mandatory. The Commissioner agrees that they may be measured less often than every 15 minutes. The suggestion that they be measured at least every 15 minutes is an advisory procedure, because procedures vary. Nevertheless, the Commissioner cautions on the need for scrupulous, timely monitoring.

12. Air supply and controls (§ 113.40(b)(10)(i)): One comment agreed with the Commissioner's desire to have the adequacy of air or water circulation established by a competent processing authority, but it noted that such determinations should also be accepted if they were made in accordance with procedures recognized by competent processing authorities.

The Commissioner agrees and has made appropriate changes here and in other similar sections of the regulation.

13. Vertical and horizontal still retorts (§ 113.40(b)(13)): A comment stated that it is not always necessary for a processor to have heat distribution data on file, but the firm may have operating and installation requirements from the manufacturer or a processing authority who does have such data on file.

The Commissioner agrees that this approach is acceptable and has made appropriate changes in the regulations.

14. Bleeders (§ 113.40(c)(5)): Two comments stated that the proposed 15-minute interval for checking the condensate bleeder is too short. One comment suggested checks at 30-minute intervals, and the other suggested that the regulations permit bleeder function to be checked at intervals established by the company to ensure adequate operation of the retort. A comment also asked for permission to use automatic alarm systems to detect condensate bleeder malfunction.

As with the requirement for measuring critical factors, the Commissioner advises that the regulations require that the condensate bleeder be checked with sufficient frequency to ensure adequate removal of condensate. The 15-minute interval for checking the bleeder is merely advisory. The Commissioner agrees that the optional use of automatic alarm systems to detect condensate bleeder malfunction is appropriate to serve as a continuous monitor, and such a provision has been incorporated.

15. Retort speed timing (§ 113.40(c)(7)): One comment noted that, in the sections concerning temperature-recording devices, the Commissioner explained how to satisfy the requirement that "a means of preventing unauthorized changes in adjustment shall be provided." The comment suggested that a statement also be included in this section to spell out satisfactory means to satisfy the requirement.

The Commissioner agrees that this was an oversight in the proposal and therefore has included such a provision here and in similar sections of this part. To prevent unauthorized changes in the retort timing speed, the regulations recognizes a lock or a notice from management, posted at or near the speed-adjustment device, which provides a warning that only authorized persons are permitted to make adjustments, as satisfactory preventive measures.

16. Emergency stops (§ 113.40(c)(8)):

a. In the case of an emergency stop, the proposal would have required that a still process be used or that all the containers be either reprocessed, repacked and reprocessed, or discarded. A comment argued that sterilizing processes other than still processes should be acceptable if an emergency stop is required; and it suggested that the regulation be changed to allow the use of other processes if they have been established to ensure commercial sterility.

The Commissioner agrees, and such a change in the regulation has been made.

b. Another comment suggested that subparagraph (iii), concerning handling emergencies, be deleted. The comment found this requirement redundant with the requirement of § 113.89 and thought it more appropriate to have all requirements concerning process deviations in a single section.

The Commissioner agrees and has deleted proposed § 113.40(c)(8)(iii) and included the requirement in § 113.89.

17. Critical factors (§ 113.40(c)(10)):

a. A comment stated that net weight measurements are appropriate as a measure of volume and headspace in homogeneous liquids, whether the containers are conventional sanitary cans or lap seam (vent hole) cans. Accordingly, the comment asked that the regulation be rewritten to permit the measurement of headspace by net weight measurements of homogeneous liquid products in conventional sanitary cans.

For a specific homogeneous liquid product, the Commissioner agrees that processes can be established to measure volume and headspace for both the conventional sanitary cans and lap seam cans on the basis of maximum net weight, taking into account the specific can end profile and other factors that affect container headspace. Therefore, the Commissioner has revised the regulation accordingly.

b. The same comment suggested that the requirement for the measurement of headspace every 15 minutes be replaced by a requirement that sampling be conducted on the basis of throughput and that the number of samples taken and the intervals of sampling be determined from standard acceptable quality level (AQL) tables.

The Commissioner agrees that the use of such methods could ensure that critical factors are measured and recorded at sufficient frequency to guarantee that the factors are within the limits specified in the scheduled process. Nevertheless, because the frequency requirement for recording the measurements is advisory, not mandatory, no change has been made in the regulation.

18. Temperature-indicating device (§ 113.40(g)(1)(i)(*a*)): One comment pointed out that this section requires thermometers and temperature-indicating devices to be tested for accuracy at least once a month, although in other sections the requirement is once a year. The operation of aseptic system does not provide any more opportunities for thermometers or temperature-measuring devices to become inaccurate than does the operation of any other system. Therefore, the comment requested that testing be required once a year or more frequently, if necessary, to ensure the accuracy of thermometers and temperature-indicating devices.

The Commissioner accepts this change but nonetheless stresses the importance of accurate temperature measurements, especially in high-temperature short-time systems.

19. Flow-diversion system (§ 113.40(g)(1)(i)(*h*)):

a. The Commissioner proposed a new section for aseptic processing and packaging systems to require that a flow-diversion valve be installed between the cooler and filler. The proposed provision would have required the system to be controlled to divert product flow away from the filler when the temperature of the product in the holding tube falls below the sterilization temperature specified in the scheduled processes. However, it would have provided an exception from the requirement for the flow-diversion valve when products with discrete particles are being processed. Two processors of aseptic foods com-

mented that the use of flow-diversion valves on the sterile side of an aseptic product processing line could result in product contamination.

Based on these comments, the Commissioner believes that the proposed flow-diversion valve requirement may have been misunderstood. The Commissioner recognizes that possibility of contamination if flow-diversion systems are inadequately designed or improperly operated, but the function of this section is to establish a provision for preventing insufficiently heated products from reaching the aseptic filler. An inspection of all domestic aseptic processing operations that have been filed with FDA confirms that all processors in this country currently use Dole aseptic canning units. All but one of these canning units have a manually operated system that can divert product from the filler. Some processors are using the diversions systems as they were supplied by the manufacturer, while other processors have modified the systems for automatic control. These inspectional observations do not support the contention of contamination. A summary of the findings of these inspections has been placed on display for public review in the office of the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane Rockville, MD 20857.

A packaging system supplier stated that, in addition to the use of a flow-diversion valve, there are a number of different technical solutions to the problem of preventing insufficiently heated products from reaching the aseptic filler. Also, one processor commented that it has successfully used a diversion system that is different from the Dole system to divert product from the filler automatically when the temperature at the holding-tube outlet drops below the scheduled process. Moreover, some aseptic processing and packaging establishments have elected not to use flow diversion when temperature drops occur in the product-holding tube. The processors usually stop the cans from entering the container filling area, switch to water, and resterilize the system, including the filler. Another processor commented that all aseptic processors using Dole aseptic canning units are supplied with manually operated systems to divert product from the filler, and these systems can handle both liquid products and products containing discrete particles.

Finally, one processor commented that it would not be opposed to a provision for flow diversion; however, it recommended that the provision focus on the diversion principle to prevent the packaging of nonsterile product, rather than on diversion hardware such as a flow-diversion valve.

For all the above reasons the Commissioner has revised § 113.40(g)(1)(i)(*h*). The Commissioner has substituted the term "flow-diversion system" for the proposed "flow-diversion valve," and such a diversion system is a requirement. The Commissioner has also eliminated the exception from the proposed requirement for a flow-diversion valve in equipment that processes products with discrete particles. In addition, the Commissioner finds that revision in § 113.40(g)(1)(ii) and (2)(ii)(*b*) are necessary. These provisions now describe the design, function, and purpose of the flow-diversion system. The revisions also recommend that the flow-diversion system be designed and instrumented to operate automatically when the temperature in the holding tube drops below the minimum temperature required in the scheduled process, when proper pressure in the product-to-product regenerator is not maintained, or when deviations from container or container closure sterilization processes occur. For any processor who does not practice flow diversion and whose product, subjected to system failure, is filled into containers, the regulation contains a provision that the product shall be segregated and that the deviation shall be handled in accordance with § 113.89 (i.e., reprocessed, destroyed, or when possible, evaluated by a processing authority for public health significance).

b. One comment interpreted the proposal for a flow-diversion valve as a substitution for the incubation requirement.

This interpretation is not the case. Diversion of product from the container-filling and -closing areas is intended to prevent underprocessed product from being packaged and to prevent contamination of those areas with underprocessed product. In sum, flow diversion is intended to provide an additional check to detect mechanical or human system operations failures that cause product contamination with microorganisms. On the other hand, the incubation of samples was not originally, and is not now, intended to substitute for current good manufacturing practices, including the record-keeping, record review, and evaluation of deviation requirements of the regulations. It is intended to provide a quality control and public health protection function.

c. Some comments indicated concern that valves or other pieces of equipment downstream from the holding tube could provide points for potential entry of microorganisms into the product.

The Commissioner agrees and therefore has added new § 113.40(g)(1)(i)(*f*) to provide for use of steam seals (or other effective barriers) at such potential access points.

CONTAINERS

20. Can seam measurements (§ 113.60(a)(1)(i) (*a*) and (*b*)): Two comments objected to making the measurement of seam thickness mandatory. One comment contended that seam thickness cannot be measured or observed using a seam scope.

As the Commissioner explained in the proposal, thickness in can seaming is critical to ensuring the manufacture of safe products, and its measurement is now required. The Commissioner recognizes, however, that if a seam scope or projector is used for can seam measurements, a micrometer must be used to measure the thickness. Therefore, the Commission has revised the regulation to make this clear.

21. Cooling water (§ 113.60(b)): The proposal would have required measurable free chlorine residue at the water discharge point of the container cooler, and it would have permitted the use of other safe chemicals or physical water treatment that has the equivalent bactericidal effect as chlorine. One comment pointed out that, even in properly chlorinated container cooling water, it is not always possible to have a measurable free chlorine residue at the water discharge. For that reason, the comment recommended that the section be reworded to require proper sanitizing of the water in cooling canals, but it felt the Commissioner should recommend, not require, a measurable residue of the chemical sanitizing agent at the water discharge point.

The Commissioner agrees, and this change in the regulation has been made.

22. Raw materials (§ 113.81(a)): Two comments stated that it would be impractical to hold raw materials until an evaluation of the microbiological quality of the product could be made.

The Commissioner did not intend that a processor keep raw materials until a plate count, for example, could be made. Rather, the Commissioner intended to list specific ways by which processors can be certain, before using such, that their raw materials and ingredients susceptible to microbiological contamination are suitable for use. The methods include receiving the materials under a supplier's guarantee or under any other acceptable means in addition to testing by the processor. The Commissioner, therefore, has changed the regulation to clarify these intentions.

23. pH (§ 113.81(e)):

a. One comment suggested that a safety factor of two-tenths of a pH unit should be included in this paragraph.

When the maintenance of pH (above 4.6) of a normally low-acid food is the basis for a scheduled process, the scheduled process must be filed with FDA under § 108.35 of this chapter, and the scheduled process, as filed, will have the necessary and appropriate safety factor as described earlier. Therefore, the Commissioner rejects this suggestion.

b. Another comment stated that the reference to the methodology for pH determinations is too restrictive because it requires the methodology described in § 114.90 (21 CFR 114.90) to be used.

The Commissioner agrees. Because the methodology in § 114.90 is advisory, the Commissioner has changed the regulation from "shall" to "should."

24. Scheduled process (§ 113.81(f)): The Commissioner has expanded this section to clarify good processing practices when the scheduled process sets forth such critical factors as water activity to prevent the growth of microorganisms not destroyed by the thermal process.

### Operations in the Thermal Processing Room

25. Thermal processes (§ 113.87(a)): A comment stated that the operating processes should be made available to the operator. In some instances, it is desirable that scheduled processes be made available to the supervisor but not to the operator.

The Commissioner agrees that it is unnecessary that the scheduled processes be available to the operator as long as they are available to the supervisor and to any duly authorized FDA employees and has made the appropriate revisions in the regulations.

26. Product traffic (§ 113.87(b)): Three comments were received concerning the proposal to establish systems for product traffic control in the retort room. One comment stated that a traffic control plan would be welcomed by all food canners and said that if such a plan exists, it should be spelled out in detail. Two comments suggested that the Commissioner eliminate the recommedation that all visual checks of the heat-sensitive indicators be recorded.

The Commissioner recognizes that there can be no single system for product traffic control that would be applicable to all plants. Nevertheless, the Commissioner believes that it is necessary for each plant to outline its own system in order to minimize the danger of unretorted product being packed as retorted product. Keeping a written record of the visual checks of heat-sensitive indicators is good practice, but that practice is not, in the Commissioner's opinion, mandatory. Therefore, no changes in this section are warranted.

27. Initial temperature (§ 113.87(c)): One comment stated that it is not necessary to determine and record preprocess temperatures when a preheater is used in a continuous retort operation.

The Commissioner advises that the effect of initial temperature is taken into account during the process of establishing as safe continuous retort operation. The instructions in this provision for filing the scheduled processes for continuous agitating retorts are clear. The minimum initial temperature of the contents at the entry to the preheater (along with other preheater operating parameters) shall be reported to ensure that the temperature complies with the established process. The initial temperature of the product must be measured at this point to ensure that the temperature is no lower than the minimum specified in the scheduled process. The instructions do not require reporting of the product temperature at the exit from the preheater (which is the entry to the first sterilizer shell).

28. Timing devices (§ 113.87(d)): One comment requested that digital clocks be allowed for timing purposes. The comment stated that digital clocks are now in use and have not been shown to be less accurate for timing purposes than other types of clocks, that there is the possibility of an inherent one-minute difference if seconds are not read with a second hand using a wall clock or if the digital clock has no place for seconds, and that the digital clock has the inherent advantage of being easier to read.

The Commissioner agrees that digital clocks are also usable and has modified the regulation to allow their use. Most digital clocks now in use, however, are not graduated in seconds. For this reason, they may be used only if the operating process of heating the food has a safety factor of one minute or greater.

29. Steam supply (§ 113.87(f)): One comment questioned whether a firm will be in violation of this section if the steam pressure falls below that validated as the minimum steam pressure for venting. This same comment suggested that the firm have a series of steam-pressure-versus-time venting schedules correlated to various lower pressures in increments of 10 pounds per square inch to correct for any pressure drops below that validated for venting. The comment also recommended that an alarm be placed on the retort steam header line to warn of an impending lowering of steam pressure.

The Commissioner agrees that venting is very important and that a firm must know the steam-pressure-versus-time relationship for venting. A firm will not be considered in violation of this provision should the steam pressure fall below the level validated as a minimum under the following conditions: (1) There is an alternate venting schedule available for the lower steam pressure; (2) the schedule has been filed with FDA; and (3) the schedule has been shown to be effective. Any significant drops in pressure will be recorded on the retort charts. For this reason, the Commissioner finds that an alarm system is not necessary and has not changed the regulation in this regard.

### Deviations in Processing, Venting, or Control of Critical Factors

30. Separate file for deviations (§ 113.89): Two comments objected to the need for processors to keep a separate file detailing all deviations in processing, venting, or control of critical factors.

Because this information must be recorded and maintained under the regulations, the Commissioner believes it is obvious that the information will have to be filed and eventually retrieved. Therefore, the information must be available for review.

The comments further stated that there does not appear to be adequate justification at this time for the Commissioner to require an entirely separate, but duplicate, filing system for such records. The Commissioner did not intend to propose a complete duplicate system of records, but rather proposed that processors maintain a separate file of process deviations to enable the processor as well as an FDA investigator to ascertain readily which products may have been underprocessed. The FDA's experience in investigating establishments demonstrates that some system which permits rapid identification of potentially underprocessed lots is necessary for efficient use of regulatory manpower. The regulation has therefore been revised to delete the requirement for a complete duplicate file of all records. Based on experience in reviewing logs in industry plants, the Commissioner concludes that a log identifying the appropriate data is sufficient.

### PROCESSING AND PRODUCTION RECORDS

31. Water activity and alternate systems (§ 113.100(a)(6) and (7)): One comment asked that these sections be deleted because they are redundant and because they place an undue emphasis on maintaining records of such critical factors as water activity and pH. Alternatively, the comment proposed a rewording and combination of the two provisions.

The Commissioner advises that if water activity and pH are used as a part of the scheduled process, their control is critical. These two provisions have been clarified, but the Com

missioner has retained the requirement in the final regulation that records about these systems be maintained.

32. Record initialing (§ 113.100(b)): One comment objected to the proposed requirement that processing records be dated, and initialed or signed, when they are reviewed by the management representative. The proposal would have required this to be done not later than one working day after the actual processing and before shipment or release of the food for distribution. As an alternative, the comment suggested a statement that could be initialed or signed by the reviewer, and that indicates that these processing and production records have been checked within one working day.

The Commissioner sees no advantage in the suggested alternative and has not accepted it.

33. Initial distribution (§ 113.100(d)): Three comments objected to the requirement that processors maintain records identifying the initial distribution of finished products on the ground that this requirement is a recall tool and is covered under § 103.35(f). One comment further stated that the present system of batch codes on shipping documents is adequate and should be acceptable.

Section 108.35(f) establishes only the general, basic requirement of maintaining records. Section 113.100(d), on the other hand, prescribes the specific good manufacturing practices that require the processor to maintain records that identify the initial distribution of finished products. The Commissioner concludes that the benefits to the consumer from this requirements are clear. It expedites the recall of dangerous or potentially dangerous products from the market (see *National Confectioner's Ass'n* v. *Califano*, 569 F. 2d 690 (D. C. Cir. 1978)).

The remaining comments requested that portions of the proposal be clarified. The Commissioner has clarified portions of the final order so that there may be better implementation of the proposed regulations. Accordingly, having evaluated all of the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended by revising Part 133 as follows:

## PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

### Subpart A—General Provisions

Sec.
113.3 Definitions.
113.5 Current good manufacturing practice.
113.10 Personnel.

### Subpart B—[Reserved]

### Subpart C—Equipment

113.40 Equipment and procedures.

### Subpart D—Control of Components, Food Product Containers, Closures, and In-process Material

113.60 Containers.

### Subpart E—Production and Process Controls

113.81 Product preparation.
113.83 Establishing scheduled processes.
113.87 Operations in the thermal processing room.
113.89 Deviations in processing.

### Subpart F—Records and Reports

113.100 Records.

AUTHORITY: Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).

### Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) "Bleeders" means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Come-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(e) "Commercial sterility": (1) "Commercial sterility" of thermally processed food means the condition achieved—

(i) By the application of heat which renders the food free of—

(a) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(b) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(2) "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Critical factor" means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(h) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(i) "Headspace, net" of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(j) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing.

(k) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.

(l) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(m) "Lot" means that amount of a product produced during a period of time indicated by a specific code.

(n) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity ($a_w$) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(o) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(p) "Operating process" means the process selected by the processor that equals or exceeds the minimum requirements set forth in the scheduled process.

(q) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(r) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.

(s) "Shall" is used to state mandatory requirements.

(t) "Should" is used to state recommended or advisory procedures or to identify recommended equipment.

(u) "Vacuum-packed products" means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.

(v) "Vents" means openings through the retort shell, controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(w) "Water activity" ($a_w$) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

**§ 113.5 Current good manufacturing practice.**

The criteria in §§ 113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

**§ 113.10 Personnel.**

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

## Subpart B—[Reserved]

## Subpart C—Equipment

**§ 113.40 Equipment and procedures.**

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening and equipped with a ⅛-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a ⅛-inch or larger bleeder which emits steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. The steam controller may be air-operated and actuated by a temperature sensor positioned near the mercury-in-glass thermometer in the retort; a steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with

steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of this pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. For horizontal still retorts, bleeders shall be located within approximately 1 foot of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.

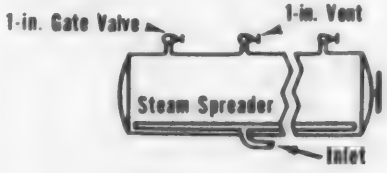
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraph (a)(12)(i)(*a*) through (*d*) and (ii)(*a*) and (*b*) of this section.

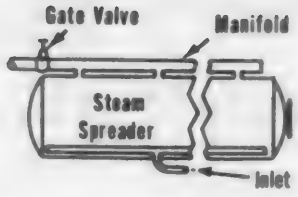
(i) *Venting horizontal retorts.* (*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.




*Specifications.* One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

*Venting method.* Vent valves should be wide open for at least 5 minutes and to at least 225° F, or at least 7 minutes and to at least 220° F.

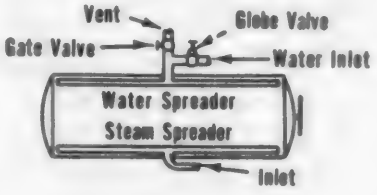
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.




*Specifications.* One 1-inch vent for every 5 feet of retort length; and vents not over 2½ feet from ends of retort; Size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

*Venting method.* Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225° F, or for at least 8 minutes and to at least 220° F.

(*c*) Venting through water spreaders.

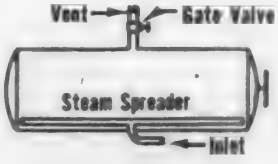



*Size of vent and vent valve.* For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

*Size of water spreader.* For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches. The number of holes should be such that their total cross-sectional area is approximately equal to the cross-sectional area of the vent pipe inlet.

*Venting method.* Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F, or for at least 7 minutes and to at least 220° F.

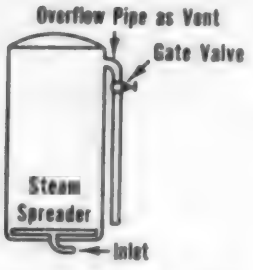
(*d*) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).




*Specifications:* A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

*Venting method:* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

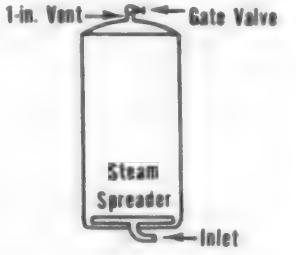
(ii) *Venting vertical retorts.* (*a*) Venting through a 1½-inch overflow.




*Specifications.* A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

*Venting method.* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F. or for at least 5 minutes and to at least 215° F.

(*b*) Venting through a single 1-inch side or top vent.




*Specifications.* A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

*Venting method.* Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F. or for at least 7 minutes and to at least 220° F.

(iii) Other installations and operating procedures that deviate from the above specifications may be used if there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date when it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording-thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts, the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the control bulb. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1½-inch clearance between the side wall of the crate and the retort wall.

(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be

made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process. Dividers, racks, trays, or other means of positioning of flexible containers shall be designed and employed to ensure even circulation of heating medium around all containers in the retort.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. Screens should be installed over all drain openings.

(9) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, e.g., by using a gage, water glass, or petcock(s). Water shall cover the top layer of containers during the entire come-up-time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(10)(i) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the come-up-time and during processing and cooling periods; the adequacy of the air or water circulation for uniform heat distribution within the retort shall be established in accordance with procedures recognized by a competent processing authority and records shall be kept on file; if air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

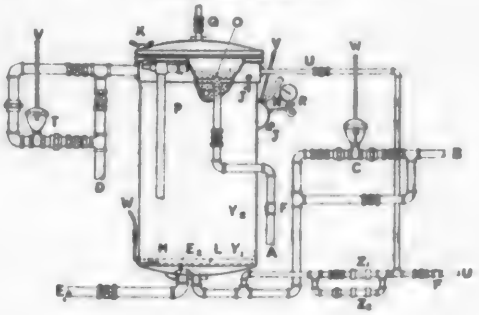
(ii) *Water circulation.* When a water circulating system is used for heat distribution, is shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross-section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warm the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(11) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

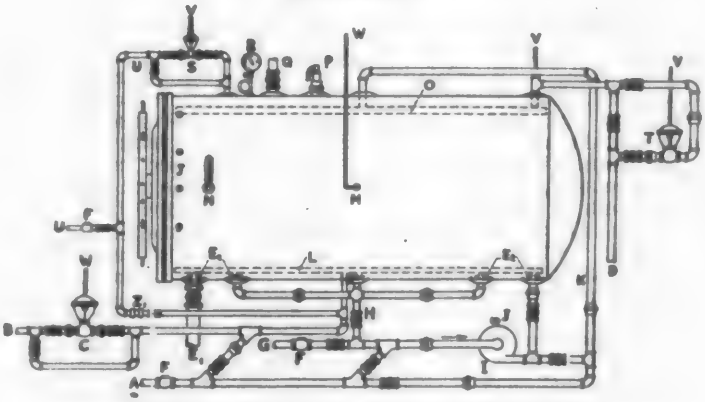
(12) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(13) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams below in this paragraph. Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, that demonstrates that the heat distribution is adequate.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
$E_1$—Drain line.
$E_2$—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature-controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
$Y_1$—Crate support.
$Y_2$—Crate guides.
Z—Constant flow orifice valve.
$Z_1$—Constant flow orifice valve used during come-up.
$Z_2$—Constant flow orifice valve used during cook.

(14) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs in indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eight inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time

a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed, or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10° F or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handing methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F, a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are used, no containers may enter the retort and the process and procedures used shall be noted on the production records.

(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lapseam (vent hole) cans may be measured by net weight determinations. The headspace of double seamed cans may also be measured by net weight determinations for homogenous liquids, taking into account the specific can end profile and other factors which affect the headspace, if proof of the accuracy of such measurements is maintained and the procedure and resultant headspace is in accordance with the scheduled process. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch-diameter opening, and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be in-

stalled either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers, at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for containing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the schedules process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Critical factors.* Critical factors specified in the schedules process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products for which deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts—(1) Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard use, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means of preventing unauthorized changes.

(6) *Air supply and controls.* Means shall be provided for introducing com-

pressed air at the proper pressure and rate, which shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vaccum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometer shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. The thermometer shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder. The mercury thermometer—not the recorder chart—shall be the references instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Each temperature-recorder bulb well shall have a 1/16-inch or large. bleeder opening which emits steam continuously during the processing period. Additional temperature-recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specified maintenance of particular temperatures in the hydrostatic water legs. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Recording of temperatures.* Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully mechanically maintained so that it operates satisfactorily.

(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(7) *Bleeders.* Bleeder openings ¼-inch or larger shall be located at the top of the steam chamber or chambers opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(8) *Retort speed.* The speed of the container-conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(a) *Temperature-indicating device.* Each product sterilizer

shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device, such as a thermocouple-recorder. Mercury-in-glass thermometers shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers and temperature-indicating devices shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer and temperature-indicating device should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to essential agreement with the standard shall be repaired or replaced. Thermometers and temperature-indicating devices shall be installed where they can be accurately and easily read. The temperature-indicating device shall be the reference instrument for indicating the processing temperature.

(b) *Temperature-recording device.* There shall be an accurate temperature recording device on each product sterilizer. The device shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Temperature-recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the desired product-sterilization temperature.

The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, a known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. A lock; or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

(c) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of ensuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(d) *Product-to-product regenerators.* When a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on the working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(g) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 inch per foot.

(h) *Flow-diversion systems.* If a processor elects to install a flow-diversion system, it should be installed in the product piping located between the product cooler and the product filler or aseptic surge tank and should be designed to divert flow away from the filler or aseptic surge tank automatically. Controls and/or warning systems should be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits. Flow-diversion systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.

(i) *Equipment downstream from the holding tube.* Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system should be equipped with steam seals or other effective barriers at the potential access points. Appropriate means should be provided to permit the operator to monitor the performance of the seals or barriers during operations.

(ii) *Operation—(a) Startup.* Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product-sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge tank by means of a flow-diversion system. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. The product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.

(c) *Loss of proper pressures in the regenerator.* When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch greater than the pressure of unsterilized product in the regenerator. In this case, product flow should be diverted away from the filler or aseptic surge tank by means of the flow-diversion system. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process and shall be reprocessed or destroyed. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Loss of sterile air pressure or other protection level in the aseptic*

*surge tank.* When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process value. Product flow to and/or from the aseptic surge tank shall not be resumed until the potentially contaminated product in the tank is removed, and the aseptic surge tank has been returned to a condition of commercial sterility.

(e) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature-indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate as established by the metering pump or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and proper performance of seam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(a) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(ii) *Operation*—(a) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated and handled in accordance with § 113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the test results should be maintained.

(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(1) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.

(2) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to ensure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled proc-

(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods shall be as established in the scheduled process. These systems shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

## Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

### § 113.60 Containers.

(a) *Closures.* Regular observations shall be maintained during production

runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

(*a*) Micrometer measurement system:

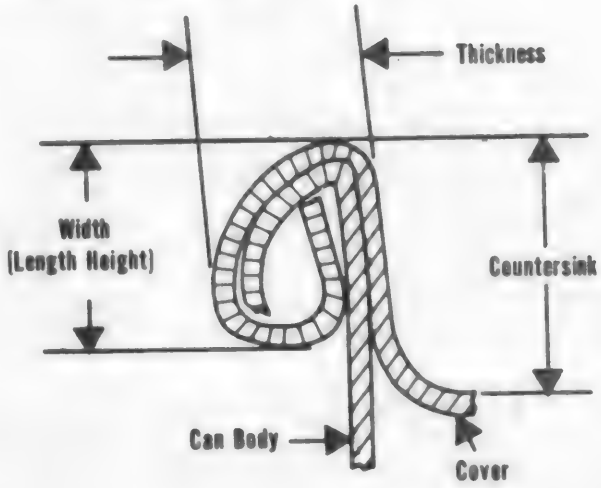
| *Required* | *Optional* |
|---|---|
| Cover hook. | Overlap (by calculation). |
| Body hook. | Countersink. |
| Width (length, height). | |
| Tightness (observation for wrinkle). | |
| Thickness. | |

(*b*) Seam scope or projector:

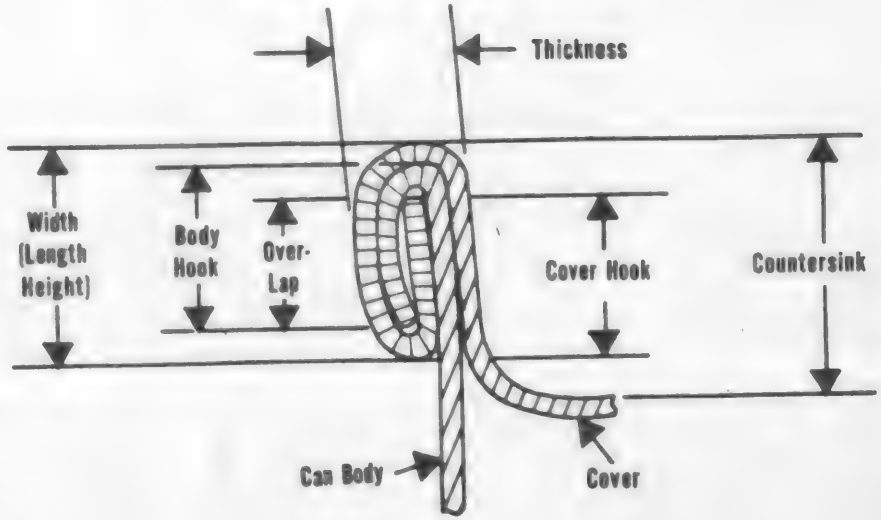
| *Required* | *Optional* |
|---|---|
| Body hook. | Width (length, height). |
| Overlap. | Cover hook. |
| Tightness (observation for wrinkle). | Countersink. |
| Thickness by micrometer. | |

(*c*) Can double seam terminology:

[4110-03-C] FIRST OPERATION ROLL SEAM




SECOND OPERATION ROLL SEAM



[4110-03-M]

(1) "Crossover": The portion of a double seam at the lap.

(2) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam.

(3) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink.

(4) "Droop": Smooth projection of double seam below bottom of normal seam.

(5) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped.

(6) "Lap": Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length = CH + BH + T − W, where
CH = cover hook
BH = body hook
T = cover thickness, and
W = seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* When cans are handled on belt conveyors, the conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated as to preserve the can seam or other container closure integrity.

## Subpart E—Production and Process Controls

### § 113.81 Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in § 114.90 of this chapter should be used.

(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity ($a_w$) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an $a_w$ greater than 0.85 and less than the $a_w$ that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

### § 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight, $a_w$, etc., that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial pro-

duction runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

**§ 113.87 Operations in the thermal processing room.**

(a) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A written record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.

(e) Clock times on recording-temperature charts should reasonably correspond to the time of day on the written processing records to provide correlation of these records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority.

**§ 113.89 Deviations in processing, venting, or control of critical factors.**

Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commerical processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commerical sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those diviations and the actions taken.

## Subpart F—Records and Reports

**§ 113.100 Processing and production records.**

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.

(6) *Food preservation methods wherein critical factors such as water activity are used in conjunction with thermal processing.* Product formulation and scheduled processes used, including the thermal process, its associated critical factors, as well as other critical factors, and results of any determinations.

(7) *Other systems.* Critical factors specified in the formulation of the product or in the scheduled process.

(b) Recording thermometer charts shall be identified by date, retort number, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later that 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

(d) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(e) Copies of all records provided for in this part, except those required under § 113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

*Effective date.* This regulation is effective May 15, 1979.

(Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).)

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 79-7689 Filed 3-15-79; 8:45 am]

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[4110-03-M]

[Docket No. 75P-0334]

## PART 114—ACIDIFIED FOODS

### Current Good Manufacturing Practice

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document prescribes the specific current good manufacturing practices (CGMP's) for acidified foods. The primary public health problem associated with these foods is the possibility of botulinal toxin formation, and this regulation will ensure safe manufacturing, processing, and packing procedures for these foods.

DATES: Effective May 15, 1979, except that the provisions of § 114.10 (21 CFR 114.10), which concerns personnel training, shall become effective on September 16, 1980.

ADDRESS: Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvin R. Johnston, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1514.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30457), the Commissioner of Food and Drugs proposed to establish CGMP regulations for pickled, fermented, and acidified foods under 21 CFR Part 114 (21 CFR Part 128g before the recodification of March 15, 1977 (42 FR 14302)).

A period of 60 days was provided for the filing of comments on the proposal, and in response to a request by three trade associations and the Spanish Ministry of Trade, the comment period was extended to November 20, 1976, by a notice published in the FEDERAL REGISTER of September 22, 1976 (41 FR 41436). The July 1976 proposal was published concurrently with a proposal to establish a new section (21 CFR 108.25 (formerly 21 CFR 90.22)) for the regulation of those foods under section 404 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344) and one to revise the CGMP regulations for low-acid canned foods (21 CFR Part 113 (formerly 21 CFR Part 128b)), which are already subject to regulation under section 404 of the act (see 41 FR 30441 and 41 FR 30444, July 23, 1976).

Under the current Part 113 CGMP regulations (amended elsewhere in this issue of the FEDERAL REGISTER), tomatoes, pears, pineapples, and their juices that have a finished equilibrium pH of less than 4.7 and figs that have a pH of 4.9 or below are not classified as low-acid foods. Therefore, they are not subject to regulation under Parts 108 and 113. The July 1976 proposal to establish Part 114 would have revoked the exemption for those foods and made them subject to the requirements of section 404 of the act and to the provisions of Parts 108 and 113 as amended by the respective July 1976 proposals cited above.

The National Canners Association (now the National Food Processors Association (NFPA)) filed extensive comments on the change proposed in the regulation to remove the exemptions from the definition of low-acid foods. After the comment period ended, NFPA requested that the comment period be reopened to allow it to develop and submit data on the final pH of certain products or classes of products to determine whether they should be exempted from the regulations. Accordingly, the comment period was reopened until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38609).

Forty-one letters, each containing one or more comments, were received from industry, trade associations, universities, Federal government agencies, members of Congress, and an individual. The comments and the Commissioner's responses are given below.

#### GENERAL

1. The United States Department of Agriculture Eastern Regional Research Center in Philadelphia commented that the proposed rules did not specify whether the discriminating pH is the pH of a composite of raw material, the mean of replicate analyses of different raw material units, or some other value.

The Commissioner disagrees. In the proposal, acidified foods were defined as foods acidified to a pH value of 4.6 or lower, and fermented foods were defined as foods prepared from low-acid ingredients and fermented to an *equilibrium* pH of 4.6 or lower. Further, the Commissioner proposed to define

low-acid foods as those with a *finished equilibrium* pH value of greater than 4.6 and a water activity of greater than 0.85. For these reasons the Commissioner believes the proposed definitions were clear; nevertheless, the Commissioner has revised the final regulation to resolve any potential misunderstanding. Because the function of these regulations is to ensure that foods are properly acidified to protect the public from *C. botulinum*, the Commissioner has revised the definition of acidified foods to state specifically that the Food and Drug Administration (FDA) is concerned with the equilibrium pH value of the finished food, and not the pH of a composite of raw material or the mean of replicate analyses of different raw material units.

Moreover, the Commissioner believes it useful to explain the interrelationship of the foods subject to regulation under section 404 of the act and the CGMP regulations for those foods.

*C. botulinum* will not normally grow in a food that has a pH of approximately 4.8 or below. pH is a measure of a food's acidity, and pH and acidity vary inversely. Because other uncontrollable variables may come into play, FDA and the food-processing industry have historically added a safety factor of 0.2 pH unit and made the basic discriminating pH value 4.6 (see 36 FR 21688, November 12, 1971, and 38 FR 2398, January 24, 1973). In addition to pH, other factors are also conducive to *C. botulinum* growth: high water activity, anaerobic environment, and ambient temperature. Certain foods are acidified to a pH of 4.6 or below (e.g., beans, peppers, puddings, and fish) to prevent growth of *C. botulinum*. These foods are designated acidified, and they are generally subject to regulation under section 404 of the act in accordance with § 108.25 (established elsewhere in this issue of the FEDERAL REGISTER) and the CGMP regulations promulgated by this notice (Part 114).

*C. botulinum* will grow in many foods when the pH is higher than 4.6 (i.e., low-acid foods), and those foods have been classified as low-acid foods. Such foods present a health hazard when they are intended for marketing as products that are intended for use in conjunction with other conditions that are conducive to botulinum growth (e.g., canned nonrefrigerated food). Low-acid foods packaged in hermetically sealed containers present this problem. These foods must be thermally processed and are subject to Part 113 and § 108.35 (21 CFR 108.35).

Also, Ohye and Christian, and Troller (see Refs. 7, 9, 10, and 11 in the preamble to the proposal) have shown that *C. botulinum* will not grow in food with a water activity of 0.85 or below. In sum, the foods subject to Part 114 are foods intended to be acidified to a pH of 4.6 or below and have a water activity that is greater than 0.85.

Most fruits have a natural pH that is below 4.6. Accordingly, these foods present no health hazard from botulism, and they are not subject to regulations either as acidified foods under § 108.25 and Part 114 or as low-acid foods under § 108.35 and Part 113. These acid and low water-activity foods are regulated under the umbrella CGMP regulations (21 CFR Part 110). To clarify their regulatory status, the Commissioner has specified their exempt status in the definition of low-acid foods.

Some fruits, however, have a pH that is above 4.6, and products made from these fruits may be intentionally acidified to an equilibrium pH of 4.6 or below. If they have a water activity that is greater than 0.85, these acidified foods may present a health hazard, and they are subject to regulation under § 108.25 and Part 114. Foods that are acidified to a pH above 4.6 and that have a water activity greater than 0.85 are considered low-acid foods. These foods, when thermally processed and packaged in hermetically sealed containers, are subject to regulation under § 108.35 and Part 113. The following table illustrates the relationship between pH, water activity, and regulatory status of most foods.

| pH (final equilibrium) | $a_w$ | Low-acid (21 CFR 113) | Acidified (not naturally) (21 CFR 114) |
|---|---|---|---|
| <4.6 | ≤0.85 | No | No |
| <4.6 | >0.85 | No | Yes |
| 4.6 | ≤0.85 | No | No |
| 4.6 | >0.85 | No | Yes |
| ≥4.7 | ≤0.85 | No | No |
| ≥4.7 | >0.85 | Yes | No |

The equilibrium pH of tomatoes varies from approximately 4.0 to 4.7, depending on the variety, ripeness, etc., and NFPA filed data with FDA showing that *C. botulinum* will not grow in tomatoe products with a pH below 4.9. For this reason, the Commissioner has specifically exempted from the definition of low-acid foods tomatoes and tomato products that have a finished equilibrium pH below 4.7 (using the 0.2 pH unit safety factor). These foods are therefore exempt from regulation under § 108.35 and Part 113; they are subject to regulation under the basic provisions of the act and the umbrella CGMP regulations. But tomatoes and tomato products with a finished equilibrium pH that is 4.7 or above are low-acid foods subject to the requirements of § 108.35 and Part 113 when those foods are intended for use in hermetically sealed containers.

2. The proposal stated that the final regulations would become effective 60 days after the date of publication, and one comment stated that 60 days is inadequate time to implement all the requirements proposed. The comment argued that if all the proposed provisions were to be required within 60 days, modifications within processing plants would be necessary, and it alleged that some processes might even have to be reestablished. All processes and modifications require time to develop. The comment therefore recommended that the Commissioner delay the effective date of the final order until 6 months after publication. Further, the comment contended that at least 18 months should be allowed to properly train a sufficient number of personnel.

The Commissioner agrees that portions of the regulation will require more than 60 days for implementation and has made adjustments for that fact. The Commissioner will require registration under § 108.25 within 120 days after the date of publication of the document (referred to above) establishing that section and require the filing of processes within 60 days after registration. The Commissioner is also allowing an effective date 18 months after the date of its publication in the FEDERAL REGISTER for the provision of § 114.10 that concerns personnel training. However, the Commissioner emphasizes that these regulations prescribe practices that are the minimum state of the art, and most processors should already be in compliance with the basic provisions.

The same comment questioned the inclusion of fermented foods in the regulation on the ground that the proposal document cited no examples in which fermentation procedure was proved to cause a food to be a health hazard. The comment went on to say that if the Commissioner desires to regulate the sanitation of plants fermenting cucumbers, the regulating should be done by implementing the appropriate sections of Part 110.

The Commissioner agrees. As the Commissioner explains in the discussion of the decision to exclude fermented foods from § 108.25 (see the preamble to the final rule establishing § 108.25, referred to above), there is insufficient evidence that commercially fermented foods require regulation under section 404 of the act. For this reason, the Commissioner has concluded that fermented foods also should not be subject to Part 114. Processing of fermented foods is covered by the umbrella CGMP regulations in Part 110.

### DEFINITIONS

3. "Acid foods" (§ 114.3(a)): One comment suggested that a new definition

for acid foods be added to distinguish between acidified foods, which are covered by this regulation, and acid foods, which are not covered.

The Commissioner agrees that such a definition is meaningful and has added it to the final regulation.

4. "Acidified foods" (§ 114.3(b)):

a. In addition to the comment on equilibrium pH discussed above, a number of comments were received concerning the definition for acidified foods. Many of these comments asked for exclusions from the definition for specific classes of foods. Exemptions were requested for such things as jams, jellies, products containing pectin, products containing small amounts of low-acid ingredients that have no significant effect on the pH of a finished product, products that have a pH below 4.0, and products that are refrigerated. One comment asked for a more specific identification of the foods to which the regulations are intended to apply.

The Commissioner agrees that some revision of the definition in general is necessary to clarify the scope of the regulations and has revised the definition, which specifies several examples of acidified foods, to cover foods that are acidified to have a finished equilibrium pH of 4.6 or lower and that have a water activity greater than 0.85. The Commissioner has now specifically excluded, however, several foods from this general definition because experience and review of the evidence show that bacteria of public health significance cannot and do not grow in these foods. The definition of acidified foods now excludes (1) jams, jellies, preserves, and other acid foods that have a water activity of 0.85 or less; (2) acid foods that contain small amounts of low-acid foods and have a resultant equilibrium pH that does not significantly differ from that of the predominant acid food (and is 4.6 or below); and (3) foods that are stored, distributed, and retailed under refrigeration.

The Commissioner refuses to exempt foods having an equilibrium pH of 4.0 or below from the definition of acidified foods because the potential for improper acidification in the preparation of these products could result in the preparation of a food that poses a significant health hazard.

b. Another comment suggested that the Commissioner add a definition for the term "low-acid food ingredients," which was used in the proposed definition of acidified foods.

Food ingredients are also foods; therefore, the Commissioner has deleted the word "ingredients."

c. One comment asked for clarification of the wording for the exclusion of salad dressings from the definition of acidified foods. It requested that the definition be revised to state that "carbonated beverages and standardized and nonstandardized dressings for salads and condiment sauces" are excluded from the coverage of Part 114.

The Commissioner agrees with the comment. "Salad dressing" is a specific standardized food. Nevertheless, many assume the term includes those foods standardized in 21 CFR Part 169 as "food dressings" as well as nonstandardized foods intended for the same use. The Commissioner, therefore, has reworded this provision of the definition to make clear that food dressings and condiment sauces are excluded from the definition if the resultant equilibrium pH does not significantly differ from that of the predominant acid or acid food.

d. One comment asked the Commissioner to delete the phrase "to prevent growth of microorganisms of public health significance" from the definition on the ground that the reason for adding acid to the food is irrelevant if the final food product achieves an equilibrium pH of 4.6 or below and is therefore safe. But another comment on the scope of the proposed definition requested that the Commissioner confirm that the definition of acidified foods does not extend to foods to which acid is added for technological purposes unrelated to preventing the growth of microorganisms.

The Commissioner believes that the crucial point is the intended equilibrium pH of the food. As long as the final food product is acidified to achieve an equilibrium pH of 4.6 or below, it makes no difference why acid is added to a food, because spore growth and toxin formation are impossible at or below that pH. For that reason, the Commissioner has deleted from the definition the phrase on the prevention of microorganism growth. The Commissioner recognizes that, in specific instances, foods to which acid is added can be exempt from the definition, and will address those instances on a case-by-case basis when petitions for exemption are filed.

e. Another comment requested that the Commissioner exempt foods with a pH higher than 4.6 from the definition of acidified foods when data show that the outgrowth of spores is prevented by acidity even at the higher pH values. The comment requested that the phrase "the food shall be acidified to pH 4.6 or lower except where a higher pH has been shown to inhibit the growth of *C. botulinum* spores" be included in the definition of acidified food.

The Commissioner has decided against including this broad language in the definition because, to date, data have been presented that support an exemption only for tomatoes and tomato products having an equilibrium pH below 4.7. Further, no evidence has been submitted suggesting that the cutoff point of 4.6 is inappropriate or unreasonable. For this reason, thermally processed foods that are packaged in hermetically sealed containers and that have an equilibrium pH greater than 4.6 are properly included under Part 113. If data are developed showing that spores of *C. botulinum* are prevented from growing in particular foods at higher pH values, the data should be used in support of the development of scheduled processes as specified in 21 CFR 113.83. When adequate data are collected, the Commissioner will determine whether to exempt the specific foods from the regulations.

5. "Fermented foods" (proposed as § 128g.1(b)): All comments received on this provision asked for exemptions from the definition for products such as vinegar, black olives, soy sauce, fermented tea, coffee, cacao, and vanilla because the *C. botulinum* growth is inhibited by other mechanisms in these fermented foods.

The Commissioner has concluded that fermented foods will continue to be regulated under Part 110 and has deleted the definition from the final regulation. Therefore, these comments are moot.

6. "Lot" (§ 114.3(c)): One comment found the definition misleading. Under the proposed definition, the term "lot" means a product produced during a period indicated by a specific code, and the requirements for coding are clearly spelled out in § 114.80(b). The comment was concerned with those instances in which acidified foods are manufactured in a multiple vat arrangment owing to potential pH problems.

The Commissioner agrees that it is inadvisable to use a common code for a multiple vat operation. If problems arise with the processing in one vat, the entire lot is suspect and must be set aside for evaluation. For this reason, processors are advised to avoid a single code for multiple vats. However, it is not always possible to code every vat in a multiple vat arrangement, and coding every vat in a multiple vat arrangement, although desirable, is not required because, should any problems arise, the entire lot could be retained. Therefore, the Commissioner has made no change in the definition of "lot."

7. "Low-acid foods" (§ 114.3(d)): As proposed, the definition for low-acid foods would not have recognized specific exemptions. In its initial comments on this notice and the proposal to revise Part 113, NFPA requested that the current exemption from the definition of "low-acid foods" for certain tomato, pineapple, pear, and fig products be maintained in the proposed definition until additional data

were available to bolster the claims for exemption. The NFPA later submitted data to prove that an equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum* in tomato products. Data on figs were also submitted, but no data were submitted on pears or pineapples.

After reviewing the data, the Commissioner agrees that an equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum* in tomato products and has changed the definition of low-acid foods to exempt tomatoes and tomato products having a finished equilibrium pH of less than 4.7 from the definition of low-acid foods. However, the Commissioner believes the data submitted on figs are inconclusive and has not made any allowance for their exemption from this regulation. If figs are not acidified, or are acidified but only to a pH above 4.6, they are low-acid foods, and if they are thermally processed and packaged in hermetically sealed containers, they are subject to Part 113. If figs are acidified to a pH of 4.6 or below, they are subject to Part 114. Because no data were submitted in support of excluding pears and pineapples, no change was made in the definition in this regard. The Commission advises that foods containing pears and pineapples will be subject to Part 110 and, depending on the pH and water activity, may be subject to § 108.25 or 108.35 and Part 113 or 114.

8. "Pickled foods" (proposed as § 128g.1(e)): One comment suggested that the reference to pickled food in the title of the regulation and in all other parts be deleted because of its redundancy. Pickles are defined in terms of acidified foods and fermented foods.

Consistent with the determination that only acidified foods should be subject to § 108.25 and Part 114, the Commissioner has eliminated the definition of the term "pickled" from both documents because the term does connote both acidified and fermented foods. However, pickled foods that are acidified are included in these regulations.

9. "Scheduled process" (§ 114.3(e)): Two comments stated that this definition is not applicable to all products covered by the regulation. Two other comments desired to have the scheduled process reflect only those conditions that are required to control pH.

The Commissioner agrees that the scheduled process may be different for different products, but concludes that factors other than pH must be controlled in order to protect the public health. Accordingly, the Commissioner has revised the definition of scheduled process to emphasize the control of pH and other critical factors, although the definition does not enumerate the other specific critical factors.

### Personnel

10. Personnel (§ 114.10):

a. Two comments requested that students who have attended schools designed to comply with the requirements of Part 113 for the training of supervisors be exempt from attending schools prescribed under this regulation. Many of the subjects covered under this regulation have already been covered in the courses presented on Part 113.

The Commissioner agrees and has reworded this section to allow persons who were certified before the publication of this final regulation to be exempt from the requirement for further schooling. However, the Commissioner recommends that all persons involved in processing acidified foods attend a course with more details on those foods to ensure that supervisors are fully knowledgeable in this area.

b. Another comment felt that the cost of training is unnecessary because the management of a firm is motivated to hire qualified personnel in order to protect the firm's products.

The Commissioner disagrees. Most manufacturers are already subject to these requirements under Part 113, but the Commissioner's experiences in the compliance program area show numerous instances of improperly acidified foods and thus suggest that supervisory personnel have not been properly trained. The Commissioner emphasizes that such training is essential to make employees cognizant of the factors involved in producing safe acidified foods.

c. A fourth comment suggested that, for practical purposes, supervisors need an extension of time for attendance at these schools because schools meeting this requirement do not now exist and will require some time to develop.

The Commissioner agrees and has allowed a period of 18 months after the date of publication of this regulation in the Federal Register for the training of supervisors.

### Processes and Controls

11. Section 114.80(a)(1):

(a) One of the critical factors in the scheduled process for acidified foods is heat processing. Because heat processing is no longer specifically mentioned in the definition of "scheduled process" (§ 114.3(e)), the Commissioner has rewritten a portion of this paragraph to clarify that the quality control procedures for the thermal processing must be sufficient to ensure that the finished food does not present a health hazard.

(b) Several comments objected to the proposed requirement that all products that purport to be, or are represented as, "pickles," "pickled," or "acidified," have an equilibrium pH of 4.6 or lower unless they are thermally processed as low-acid foods. They point out that many perishable foods rely on refrigeration as the primary mode of preservation during their normal shelf-life and that it is not equitable to exclude "half sour" pickles from introduction into interstate commerce.

The Commissioner agrees that these products are safe when properly refrigerated and has reconsidered the proposed requirement to exclude pickled products from interstate commerce if they have a pH greater than 4.6 and are not thermally processed as low-acid foods. Although the Commissioner notes that some consider that pickles having a pH above 4.6 may constitute a potential public health problem, the agency has no evidence to support that contention. The Commissioner, therefore, has deleted from the regulation the requirement that products that purport to be, or are represented as, "pickles," "pickled," or "acidified," must have an equilibrium pH of 4.6 or lower unless they are thermally processed as low-acid foods. On the other hand, the Commissioner advises, foods that have a pH above 4.6 are covered under 21 CFR Part 110. They are also covered under 21 CFR Part 113 if they are thermally processed and packaged in hermetically sealed containers. The Commissioner has revised the regulation to exclude foods that are stored, distributed, and retailed under refrigeration.

12. Section 114.80(a)(2): One comment suggested that maximum time intervals for the frequency of pH testing be spelled out and that a recording pH meter be required on those processes of a continuous nature.

The Commissioner advises that sufficient control of pH is required to ensure that the finished equilibrium pH of a given food is not higher than 4.6. The manner in which the controls are accomplished is left up to the manufacturer. Also, the manufacturer may use any of the acceptable methods for measuring the pH in continuous operations, and the use of a recording pH meter, although desirable, is not mandatory. The Commissioner has not made the suggested changes in the regulation, but rather has clarified the requirement.

13. Dilution of brine (proposed as § 128g.7(c)(4)): One comment suggested that this paragraph, concerning the dilution of brine in tanks, be deleted because it is unnecessary to the protection of the public health. A significant dilution of brine in tanks may result in either improper fermentation or improper curing owing to a reduced amount of salt.

Because fermented foods are no longer covered by this part, the Commissioner has deleted this paragraph.

14. Section 114.80(a)(5): One comment recommended deleting the requirement that the final packaging operation be in an enclosed building.

The Commissioner has deleted this requirement from this regulation because requirements for general sanitation, plants, and grounds are included in the "umbrella" CGMP regulations, Part 110. Part 110 does not require that the final packaging operation be in an enclosed building.

15. Fermentation and salt curing (proposed as § 128g.7(b)): This provision is applicable only to fermented foods and has accordingly been deleted.

16. Coding (§ 114.80(b)): One comment suggested that it is unnecessary to include product identification in a code on a container in which the food product is visible, and the comment asked that the regulation be changed to exempt such products.

The Commissioner rejects the comment. Coding permits rapid and positive identification of a suspected food if a recall is needed. Most causes of recalls simply cannot be detected by visual inspection of the food in the container, and *C. botulinum* definitely cannot be observed.

### Establishing Scheduled Processses

17. Establishing scheduled processes (§ 114.83): To emphasize the importance of this provision, the Commissioner has created this new section from proposed § 114.80(b)(1) (formerly § 128g.7(b)(1)).

### Deviations From Scheduled Processes

18. Deviations from scheduled processes (§ 114.89):

a. One comment asked for clarification of the term "fully rework," and it asked that a time limit be set to ensure speedy followup on deviant lots. Another comment stated that it would be unsafe to allow reworking if the product has been at a pH above 4.6 for more than 12 hours.

In response to these comments, the Commissioner has made changes to clarify the regulation and has eliminated the term "fully rework." The Commissioner has added the requirement that reprocessing be done by a process established by a competent processing authority. Adding this provision will eliminate the necessity of establishing a time limit on reprocessing because the processing authority will take all safety aspects into consideration in determining whether a new process can be established.

b. Another comment asked that the words "or otherwise" be deleted from the requirement for the "ph * * * as determined by a qualified analyst or otherwise." The comment stated that only a qualified analyst should be permitted to examine the records to determine whether the equilibrium pH is above 4.6.

Apparently the wording has caused some misinterpretation of the regulation. The Commissioner did not intend that only a qualified analyst be permitted to examine the records to determine whether the equilibrium pH is above 4.6. Rather, the regulation, indeed the entire Part 114, is designed to provide maximum public protection against botulism. The regulations require personnel training and are aimed at requiring everyone in the production process to be able to participate in, or to initiate, the public protection elements of the regulations. For these reasons, the regulations are designed so that a person who is properly trained, but who is not a qualified analyst, is capable of examining the records. Because controls to be used in processing the foods are outlined in § 114.80(a)(2) and records are listed in § 114.100, the Commissioner has removed from § 114.89 reference to the means by which pH is determined or disclosed. Nevertheless, when a deviation from the scheduled process occurs, the Commissioner intends to require measurement of the food's pH by one of the options outlined in §§ 114.80(a)(2) and 114.90, and proper recording of the pH.

19. Methodology (§ 114.90):

a. Two comments questioned the value of including a methodology section in the regulation. One comment stated that a methodology section is unnecessary and costly because it will require additional labor to check and recheck instruments. A second comment claimed that better pH methodology can be obtained by reference to appropriate texts, reference books and, most importantly, the instruction manual provided by each manufacturer for the care and operation of its particular pH measuring devices.

Testing food to determine its pH or acidity is necessary to ensure that proper controls and manufacturing practices have been used in processing the food. The Commissioner reaffirms the position that describing appropriate methods for measuring pH or acidity of foods benefits many processors, because experience shows many processors lack this knowledge. A review of available manufacturer's instructions, owner's manuals, and reference books (including Official Methods of Analysis of the Association of Official Analytical Chemists) disclosed that those publications do not list detailed instructions for testing the variety of food systems that are covered by this regulation. Therefore, the Commissioner concludes that this methodology section, with some editorial changes, is necessary and is retaining it as a part of the final regulation. The Commissioner further advises that the regulation does not preclude the use of instrument manufacturer's instructions, owner's manuals, or published scientific literature. Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, those specified in the regulation.

b. A comment objected to the mandatory requirement that the methods given in this section be used if the pH is higher than 4.0.

The Commissioner agrees that methods other than those given in this regulation may be used to determine the pH of the food and has eliminated the mandatory requirement that this prescribed potentiometric method be used. Nevertheless, the Commissioner still requires that some potentiometric method be used to measure the pH of foods that have a finished equilibrium pH above 4.0, because the other available methods are not sufficiently sensitive.

c. A number of other comments suggested minor changes in the methodology presented in the proposal.

Because most of these changes will help clarify the methodology, the Commissioner has made the appropriate changes.

### Records

20. Section 114.100(a): Several comments suggested that this section concerning records of the examination of raw materials, packaging materials, and finished products be eliminated or revised because the records are unrelated to the critical factors in an adequate process and are unrelated to safety.

The Commissioner believes that maintaining records covering sanitation and quality control testing is necessary. For this reason, the Commissioner declines to revise the regulation.

21. Section 114.100(b): Two comments asked that this paragraph be reworded to require maintenance of only those records relating to food safety. One comment recommended that records "showing adherence to scheduled processes" be substituted for "covering processes intended to pasteurize or otherwise heat treat products."

The Commissioner basically agrees with the comments and has changed this paragraph in the regulation accordingly.

22. Section 114.100(c): Two comments stated that there did not appear to be adequate justification to require an entirely separate, and duplicate, filing system of records.

Based on experience regulating the low-acid canned food industry, the Commissioner concludes that a separate file of process deviations must be kept to enable the processor, as well as an FDA investigator, to ascertain readily which products may have been underprocessed. However, a completely duplicate file of all records is unnecessary. A log identifying the appropriate data will suffice, and the Commissioner has changed the regulation accordingly.

23. Section 114.100(d): Three comments objected to the requirement that records be maintained to identify the initial distribution of finished products on the ground that this requirement is a recall tool and is therefore covered under § 108.25(e).

The Commissioner believes the comment has misunderstood the interaction between Parts 108 and 114. Section 108.25(e) established the general basic requirement that the manufacturers of acidified foods develop a program and maintain records on product distribution for recalling products that may be injurious to health based on considerations of section 404 of the act. But § 108.25(e) does not specify the need to maintain records to identify the initial distribution of finished products, which may arise for numerous other reasons. Section 114.100(d) and analogous provisions (§§113.100(d) (proposed as § 128b.8(d)) and 118.100(c))) will expedite and have expedited the recall of dangerous or potentially dangerous products from the market. Their benefits to the consumer are apparent (see the Commissioner's comments in the preamble to the final rule establishing recall policy (43 FR 26202, June 16, 1978)). Therefore, the Commissioner rejects the suggestions in the comments and has made no change in the regulation.

24. Section 114.100(e): One comment recommended that the records should be kept for a period of 3 years instead of "an additional 2 years."

The Commissioner agrees and has made the appropriate change in the regulation.

All other comments have been carefully considered by the Commissioner and, when deemed appropriate, have been incorporated into the regulation. In addition to amending the proposal to reflect the comments received, the Commissioner has made other modifications found to be necessary for implementing the proposed regulation. Accordingly, having evaluated the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act, (secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding a new Part 114 to read as follows:

# PART 114—ACIDIFIED FOODS

### Subpart A—General Provisions

Sec.
114.3 Definitions.
114.5 Current good manufacturing practices.
114.10 Personnel.

### Subparts B–D—[Reserved]

### Subpart E—Production and Process Controls

114.80 Processes and controls.
114.83 Establishing scheduled processes.
114.89 Deviations from scheduled procedures.
114.90 Methodology.

### Subpart F—Records and Reports

114.100 Records.

AUTHORITY: Secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a)).

## Subpart A—General Provisions

### § 114.3 Definitions.

For the purposes of this part, the following definitions apply.

(a) "Acid foods" means foods that have a natural pH of 4.6 or below.

(b) "Acidified foods" means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity ($a_w$) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled ————." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage fo this part.

(c) "Lot" means the product produced during a period indicated by a specific code.

(d) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity ($a_w$) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(e) "Scheduled process" means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

(f) "Shall" is used to state mandatory requirements.

(g) "Should" is used to state recommended or advisory procedures or to identify recommended equipment.

(h) "Water activity" ($a_w$) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

### § 114.5 Current good manufacturing practice.

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in Part 110 of this chapter, apply in determining whether an article of acidified food is adulterated (1) within the meaning of section 402(a)(3) of the act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food, or (2) within the meaning of section 402(a)(4) of the act (21 U.S.C. 342(a)(4)) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

### §114.10 Personnel.

All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. The Commissioner will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and Part 113 of this chapter before March 16, 1979, to be in compliance with the requirement of this section.

## Subparts B–D—[Reserved]

## Subpart E—Production and Process Controls

### § 114.80 Processes and controls.

(a) *Processing operations.* The manufacturer shall employ appropriate quality control procedures to ensure that finished goods do not present a health hazard.

(1) Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of nonhealth significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of nonhealth significance (in lieu of thermal processing).

(2) Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. Measurement of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or colorimetric methods. If the finished equilibrium pH of the food is above 4.0, the measurement of the finished equilibrium pH shall be by a potentiometric method, and the in-process measurements by titration or colorimetry shall be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, then the measurement of acidity of the final product may be made by any suitable method. Special care should be taken when food ingredients have been subjected to lye, lime, or similar high pH materials.

(3) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:

(i) Blanching of the food ingredients in acidified aqueous solutions.

(ii) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained.

(iii) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.

(iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.

(v) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(4) Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination.

(b) *Coding.* Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one of the following bases: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

### § 114.83 Establishing scheduled processes.

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

### § 114.89 Deviations from scheduled processes.

Whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall either: (a) Fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product; (b) thermally process it as a low-acid food under Part 113 of this chapter; or (c) set aside that portion of the food involved for further evaluation as to any potential public health significance. The evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe, or be destroyed. A record shall be made of the procedures used in the evaluation and the results. Either upon completion of full reprocessing and the attainment of a safe food, or after the determination that no significant potential for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be destroyed.

### § 114.90 Methodology.

Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, the following:

(a) *Potentiometric method for the determination of pH*—(1) *Principles.* The term "pH" is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then comparing that measurement to an emf measurement of a sample of the solution to be tested.

(2) *Instruments.* The primary instrument for use in pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage is unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to ensure proper operation of battery operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

(3) *Electrodes.* The typical pH meter is equipped with a glass membrane electrode and a reference electrode or a single probe combination electrode. Various types of electrodes designed for specific uses are available. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

(i) *Care and use of electrodes.* Calomel electrodes should be kept filled with saturated potassium chloride solution or other solution specified by the manufacturer because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in buffer solution, distilled or deionized water, or other liquid specified by the manufacturer for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with water before immersing in the standard buffers and rinsed with water or the solution to be measured next between sample determinations. A lag in meter

response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary and may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated two times, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with water and blotted with soft tissue before proceeding with the standardization.

(ii) *Temperature.* To obtain accurate results, a uniform temperature should be maintained for the electrodes, the standard buffer solutions, and the samples. Tests should be made at a temperature between 20° and 30° C, the optimum being 25° C. Any temperature determinations made without meter compensation may affect pH values. An automatic temperature compensator may be used.

(iii) *Accuracy.* The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually ±0.05 pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately ±0.01 pH unit and a reproducibility of ±0.005 pH units.

(4) *General procedure for determining pH.* When operating an instrument, the operator should use the manufacturer's instructions and should observe the following techniques for pH determinations:

(i) Switch the instrument on and allow the electronic components to warm up and stabilize before proceeding.

(ii) Standardize the instrument and electrodes with commercially-prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(c), page 943.[1] Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature (room temperature is near 25°C).

(iii) Rinse the electrodes with water and blot, but do not wipe, with soft tissue.

(iv) Immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution until the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0, or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(e), page 943.[1] Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument.

(v) Indicating electrodes may be checked for proper operation by first using an acid buffer and then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25°C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(f), page 943.[1] The pH reading should be within ±0.3 units of the 9.18 value.

(vi) The pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this shorting is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than ±1.5 pH unit from center scale.

(5) *Determining pH on samples.* (i) Adjust the temperature of the sample to room temperature (25°C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization.

(ii) Rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes; therefore, it is advisable to clean and standardize the instrument frequently. When oily samples cause fouling problems, it may become necessary to rinse the electrodes with ethyl ether.

(iii) Determine two pH values on the well-mixed sample. These readings should agree with one another to indicate that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

(6) *Preparation of samples.* Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semisolid in character. The following are examples of preparation procedures for pH testing for each of these categories:

(i) *Liquid and solid component mixtures.* Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) inclined at a 17- to 20-degree angle. Record weight of the liquid and solid portions and retain each portion separately.

(a) If the liquid contains sufficient oil to cause electrode fouling, separate the layers with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25° C and determine its pH.

(b) Remove the drained solids from the sieve, blend to a uniform paste, adjust the temperature of the paste to 25° C and determine its pH.

(c) Mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25° C and determine the equilibriated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25° C, and determine the equilibriated pH.

(ii) *Marinated oil products.* Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25° C.

(iii) *Semisolid products.* Food products of a semisolid consistency, such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. If more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iv) *Special product mixtures.* For special product mixtures such as antipasto, pour off the oil, blend the remaining product to a paste, and determine the pH of the blended paste. If

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044.

more fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(7) *Process pH determination.* Obtain sample portions of material for pH determination.

(i) For process liquids, adjust the temperature of the liquid to 25° C and determine the pH by immersing the electrodes in the liquid.

(ii) Drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iii) If enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine the equilibrated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25° C, and determine the equilibrated pH.

(b) *Colorimetric methods for the determination of pH.* This method may be used in lieu of the potentiometric method if the pH is 4.0 or lower.

(1) *Principle.* The colorimetric method for pH involves the use of indicator dyes in solutions that gradually change color over limited pH ranges. An indicator that has the greatest color change at approximately the pH of the sample being tested is selected. The pH is determined by the color of the indicator when exposed to the sample under test.

(2) *Indicator solutions.* Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10-milliliter portions of the sample solution. Colors should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colors being compared thereon with a set of color standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH.

(3) *Indicator paper.* A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change color and an approximate pH can be determined by comparison with a standard color chart.

(c) *Titratable acidity.* Acceptable methods for determing titratable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, sections 22.060–22.061, page 401.[1] The procedure for preparing and standardizing the sodium hydroxide solution is described in the same publication, sections 50.032–50.035, page 946.[1]

## Subpart F—Records and Reports

§ 114.100 Records.

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines or action levels.

(b) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in paragraphs (b), (c), and (d) of this section shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.

*Effective date.* Except for the provisions of § 114.10, which concerns personnel training and which shall become effective September 16, 1979, this final regulation shall become effective May 15, 1979.

(Secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a)))

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Regulatory Affairs.*

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[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044.